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An Empirical Investigation into Checklist Use in Surgery

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Doctor of Philosophy in Medical Sciences

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Declaration

This thesis is submitted to the *University of Warwick* in support of my application for the degree of Doctor of Philosophy. It has been composed by myself and has not been submitted in any previous application for any degree.

My academic supervisors for the PhD were:

- Professor Damian Griffin
- Dr. Mark-Alexander Sujan
- Dr. Harbinda Sandhu

In addition, Professor Charles Hutchinson provided guidance on thesis writing and structure.

The work presented (including data generated and data analysis) was carried out by me except in the cases outlined below:

Chapter 2: Checklists: A Cognitive Artefact in High-Risk Industries and *Chapter 3: Methods for Studying Surgical Checklist Use and Associated Outcomes: A Scoping Review*: academic librarian support (Samantha Johnson and Paula Younger) for literature search strategy and Endnote X9 citation manager.

Chapter 5: Empirical Study I: Direct Observation of WHO Surgical Safety Checklist in use in UK Operating Theatres: Data collection was supported by research colleagues as part of the S3 Project. Data analysis was conducted by the S3 Project Statistician. See below for S3 Project team members and roles:

Chief Investigator: Mr P McCulloch (Quality, Reliability, Safety and Teamwork Unit, Nuffield Department of Surgical Sciences, University of Oxford, Oxford, OX3 9DU, UK)

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- Part-time Researchers: L. Bleakley and J. Matthews (externally employed / no affiliation)
- Intervention Support: S. New (Saïd Business School, University of Oxford, Oxford, OX3 9DU, UK)
- S3 Project Statistician: G. Collins (Centre for Statistics in Medicine, University of Oxford, Oxford, OX3 9DU, UK)

Chapter 6: Empirical Study II: Distributed Cognition in the Operating Theatre:
senior scrub nurse (anonymous) support for validation of the study data.

Abstract

Surgical care is increasing on a global scale. Considering the complexities of the operating theatre environment and the increasing demands on team performance, knowledge must be advanced to ensure that safe surgical care is consistently delivered.

Surgical safety checklists are used as part of standard practices in operating theatres in England. However, their overall contribution to patient safety is under global scrutiny.

Over the last decade, benefits and pitfalls have been raised, which contribute to an expanding list of barriers and facilitators targeted to improve surgical checklist implementation. Issues of compliance and variable team performance have been studied. To date, no conclusive evidence has been provided to support the continued use or abandonment of surgical checklists.

This research aimed to investigate how surgical checklists are used in practice. Two empirical studies were conducted in a mixed methods approach:

- *Empirical Study I* applied direct observation to investigate an official checklist in order to establish current practice of checklist use and quality of performance.
- *Empirical Study II* applied an ethnographical approach to investigate an unofficial checklist in order to understand how it is used as an artefact within the joint cognitive system of the operating theatre.

The findings of this research suggest that the use of surgical checklists is variable and complex. The identified issues support the need for a shift in investigations to focus on how surgical checklists are used in practice rather than measuring success factors as a result of their use.

This research contributes important findings: both in the methodological and analytical approach to investigating checklist use, and to the current understanding of how checklists are used in surgery. Extensive evidence is provided on actual practice with suggested opportunities for redesign to inform current and future surgical checklist use. Evidence-based recommendations are proposed for future work.

Word count: 297/300

Abbreviations

AI	Artificial Intelligence
AT	Activity Theory
CLABSI	Central Line-associated Blood Stream Infection
DCog	Distributed Cognition
DiCoT	Distributed Cognition for Teamwork
DoH	Department of Health
FAI	Femora-Acetabular Impingement
HCI	Human-Computer Interaction
HF	Human Factors
ICU	Intensive Care Unit
IoM	Institute of Medicine
i.q.r	InterQuartile Range
JCAHO	Joint Commission on Accreditation of Healthcare Organizations
MeSH	Medical Subject Heading
NICE	The National Institute for Health and Care Excellence
NIHR	National Institute for Health Research
NHS	National Health Service
NPSA	National Patient Safety Agency
NRLS	National Reporting and Learning System
P	Probability
PSI	Patient Safety Incidents
SA	Situated Action
SSC	Surgical Safety Checklist
SURPASS	SURgical PATient Safety System
UK	United Kingdom
VTE	Venous Thromboembolism
WAD	Work-As-Done
WAI	Work-As-Imagined
WHO	World Health Organization
WHO SSC	World Health Organization Surgical Safety Checklist

Research and Training

I have undertaken the following training during the period of my study:

1. 2011/2012: MH930-20 Qualitative and Comparative Research Methods in Health
2. 2013/2014: MD915-20 Understanding Research and Critical Appraisal in Healthcare (Distance Learning)
3. EndNote X9 Training

I have attended the following conferences during my period of study:

1. Flight Safety Conference, Oklahoma City, Oklahoma, USA, 2011.
2. Flight Safety Conference, London, UK, 2011.
3. Human Factors and Ergonomics Society Annual Meeting. 55th International Annual Meeting, Red Rock Hotel, Las Vegas, Nevada, USA, September 19–23, 2011.

Research Outputs

Parts of this thesis have already been published:

1. Pickering SP, Robertson ER, et al. Compliance and use of the World Health Organization checklist in UK operating theatres. *British Journal of Surgery*. 2013;100(12):1664-70.

Publications related to this thesis:

1. Flynn LC, McCulloch PG, et al. The safer delivery of surgical services program (S3): Explaining its differential effectiveness and exploring implications for improving quality in complex systems. *Annals of Surgery*. 2016;264(6):997-1003.
2. Hadi M, Robertson E, et al. Evaluation of surgical team performance in elective operative theatres. *International Journal of Surgery*. 2011;9(7):538.
3. McCulloch P, Morgan L, et al. Programme Grants for Applied Research. Safer delivery of surgical services: a programme of controlled before-and-after intervention studies with pre-planned pooled data analysis. Southampton (UK): NIHR Journals Library; 2016.
4. McCulloch P, Morgan L, et al. Combining systems and teamwork approaches to enhance the effectiveness of safety improvement interventions in surgery: The safer delivery of surgical services (S3) program. *Annals of Surgery*. 2017;265(1):90-6.
5. Morgan L, Hadi M, et al. The effect of teamwork training on team performance and clinical outcome in elective orthopaedic surgery: A controlled interrupted time series study. *BMJ Open*. 2015;5(4):e006216.
6. Morgan L, New S, et al. Effectiveness of facilitated introduction of a standard operating procedure into routine processes in the operating theatre: A controlled interrupted time series. *BMJ Quality & Safety*. 2015;24(2):120.
7. Morgan L, Pickering S, et al. Observing and Categorising Process Deviations in Orthopaedic Surgery. *Proceedings of the Human Factors and Ergonomics Society Annual Meeting*. 2011;55(1):685-9.

8. Morgan L, Pickering SP, et al. A combined teamwork training and work standardisation intervention in operating theatres: Controlled interrupted time series study. *BMJ Quality & Safety*. 2015;24(2):111-9.
9. Morgan L, Robertson E, et al. Capturing intraoperative process deviations using a direct observational approach: The glitch method. *BMJ Open*. 2013;3(11):e003519.
10. Robertson E, Hadi M, et al. The development of process maps in the training of surgical and human factors observers in orthopaedic surgery. *International Journal of Surgery*. 2011;9(7):549.
11. Robertson E, Morgan L, et al. Quality improvement in surgery combining lean improvement methods with teamwork training: A controlled before-after Study. *PLOS ONE*. 2015;10(9):e0138490.
12. Robertson E, Hadi M, et al. Oxford NOTECHS II: A modified theatre team non-technical skills scoring system. *PLOS ONE*. 2014;9(3):e90320.

As part of this thesis, I have presented the work at the following conferences:

1. Flight Safety Conference, Oklahoma City, Oklahoma, USA, 2011. (Title: Complacency and Checklist Discipline: WHO Surgical Safety Checklist Use Preliminary data presented)
2. Flight Safety Conference, London, UK, 2011.
(Title: Complacency and Checklist Discipline: WHO Surgical Safety Checklist Use Preliminary data presented)

Chapter 1 Introduction

1.1 Overview of the Chapter

In this chapter, an overview of the selected research area will be provided to introduce the context of this thesis. More specifically, a summary will be provided as to why this area is of importance and how this research may contribute to the advancement of knowledge and understanding of how checklists are used in surgery. The overall aim of this research is to inform redesign opportunities for existing surgical checklist use, propose recommendations for the design of future surgical checklist use, and to suggest future work in this area.

1.2 Declarations

None to declare for this chapter.

1.3 Overview of the Selected Research Area

There continues to be significant focus on the need for safer surgery improvements,¹⁻³ with considerable emphasis on reducing medical errors and increasing the importance of optimal patient safety.² According to Haynes et al, 234 million operations are estimated to be performed yearly.¹ Surgery is risky due to a high number of adverse events which cause significant harm to patients. An adverse event is defined as any event or circumstance leading to unintentional harm or suffering.⁴ A substantial number of patients have been reported to experience adverse events during delivery of medical care. In the world, 42.7 million patients are estimated to experience adverse events each year.⁵ Adverse events have varying levels of impact on patients; at the extreme end of the scale, fatal adverse events (catastrophic events per exposure) have been reported at 1 per 10,000.⁶⁻⁸ Therefore, it is essential that the high number of adverse events are addressed, reduced, and eventually eradicated as it is predicted that the number of operations will continue to increase on a global scale. Increased surgical complications are a considerable cause of death and disability around the world,⁷ which are devastating to patients.¹ These events are not only costly to the healthcare industry, they also have a personal impact on healthcare professionals, leaving them with feelings of guilt as a second victim in the adverse event aftermath.⁹

In an attempt to combat the occurrence of adverse events and related issues, patient safety improvement initiatives launched the introduction of surgical checklists after their success in other high-risk industries such as aviation. One of the most famous surgical checklists introduced is the World Health Organization (WHO) Surgical Safety Checklist (SSC).¹⁰ The WHO SSC, a three part checklist containing nineteen safety critical items was implemented with ambitious objectives, primarily to reduce surgical complications and mortality rates by improving theatre team communication.^{1,10} Initially the checklist showed promising results and to this day it is increasingly used around the world and encouraged by the WHO. Since its introduction, other surgical checklists followed as a popular quality and safety improvement tool.

However, over the last decade, initial successes associated with surgical checklists have declined leading to the investigation of barriers and facilitators to surgical checklist success. Most of the work in this area has focused on the effectiveness of surgical checklist implementation, specifically addressing the associated improvements in outcome measures such as reductions in clinical complications. More recent work has explored perceptions and attitudes towards surgical checklists use; however, limited investigation has been conducted on how surgical checklists are used in practice. Therefore, through empirical studies, this research investigates how theatre team members use surgical checklists in practice. As global concern for patient safety continues, this research aims to advance knowledge in this area.

Seminal healthcare reports, which were released almost two decades ago detailed alarming error rate figures.^{2,11} The healthcare industry reacted strongly by channelling substantial effort into identifying areas for improvement in surgery, with the primary aim of reducing clinical errors and resulting harm to patients.

A common approach to error management in high-risk industries is to learn from previous events by identifying past errors, issues, risks, and risk potential;¹² this learning is possible through reporting systems. Reporting systems can be mandatory, voluntary, confidential, or open. These reporting systems provide a well-established method for communicating issues in the aviation¹³ and nuclear industries.¹⁴ The healthcare industry adopted this reporting approach through the *National Patient Safety Agency (NPSA)*, which was created in 2001 to coordinate efforts across the United Kingdom (UK) in reporting and learning from clinical errors and problems.¹⁵ Through the NPSA, the *UK National Health Service (NHS)* had the largest database of patient safety incidents (PSIs) in the world, reported via the National Reporting and Learning System (NRLS), with a repository of 900,000 errors annually.⁸ A vast amount of information was shared within this forum, recognised as beneficial to the efforts of reducing patient harm when NHS England commissioned a two-year development programme by the *Centre for Health Policy, the Imperial College London*, to improve the reporting system.¹⁶

Analysis of the issues found in error reports supports identification and understanding of the factors contributing to incidences, enabling evidence-based error reduction and management strategies to be implemented. Behaviours of theatre team members and team performance are frequently reported as a factor that may contribute to patient safety improvements; therefore, healthcare initiatives focus on methods to improve these aspects.¹⁷⁻

²³ Traditionally, theatre team performance was assessed by technical skills and competencies within trained disciplines. However, non-technical aspects of theatre team performance are more widely recognised as essential for successful surgery and thus have a positive impact on patient safety.²⁴⁻³² Non-technical skills place emphasis on individual behaviours and interactions between team members, including effective communication, decision-making, situational awareness, and leadership.

Haynes et al explain that surgical complications are often preventable, although behavioural changes and system changes are typically required.³³ One of the main aims of implementing checklists into surgical settings was to improve theatre team performance by standardising working practices and for improvements in teamwork and communication.^{22,34-37} The concept of surgical checklists driving behavioural changes supports their benefit as patient safety improvement tools; however, the complexity of identifying specific issues for improvement via the use of checklists is multifaceted. Theatre teams comprise of a multi-disciplinary group of individuals, primarily consisting of a core team of surgeons, the anaesthetic team, and nursing staff. Individually and collectively, each team member has a specific role to play in contributing to the surgical process. The surgical process consists of more than the surgical procedure. It encompasses all wider system aspects with internal and external influences. Therefore, efficient and effective teamwork and communication are essential within this complex, dynamic, and high-risk work setting.³⁸⁻⁴¹

In general, checklists are implemented as standard and work as part of the norm in many high-risk work settings including the aviation, nuclear, rail, and defence industries. Historically within these industries, substantial effort has been invested into checklist design, development, and implementation to

ensure integration with existing work practices. However, in surgical settings, checklist success is continually reported as variable and below an expected standard. Research is making progress to address reasons for this, by exploring some of the barriers and facilitators to checklist success.^{42,43} Areas for improvement mainly focus on cultural issues,⁴⁴⁻⁴⁶ teamwork, and communication,⁴⁷ which all provide insight for improved surgical checklist design, implementation strategies, and the supporting systems. However, little research comprehensively explores how theatre teams use surgical checklists in practice in support of their work. Bosk et al state that implementation of checklists without understanding how they work or why they work could be detrimental to patient safety.⁴⁴

Overall, surgical checklists, as with any checklist intervention, are perceived as effective given their simplistic concept. In addition, they are viewed as relatively low cost to design and implement, although the reality of this has varying levels of complexity, and a multitude of factors are relevant to ensure their accuracy and sustainability. Extensive research has focused on surgical checklists and more specifically on the WHO SSC by investigating and reporting successes and shortfalls. Since implementation, a notable decline in successful outcomes has been found through these studies, raising concerns for surgical checklist sustainability.^{44,48} However, how to efficiently measure checklist success is currently unknown.

Investigating how checklists are used by theatre teams in practice could greatly advance understanding of the link between the aims of the checklist and the reality of their use. The study of work-as-imagined (WAI) and work-as-done (WAD) provides a foundation for this research as it aims to understand how planned work and actual work matches or contrasts.⁴⁹ WAI is how the work is expected to be performed, and WAD is how the work is performed in practice. Application of this work improves the understanding of how humans use checklists within a work setting.⁵⁰

In addition to referring to concepts of WAI and WAD, further understanding can be gained through application of a supporting theory. This enables a

framework to investigate how checklists are currently used in practice by theatre team members. This will contribute to the identification of existing issues with checklist use by highlighting what currently works and identifying areas for improvement. The theoretical framework of Distributed Cognition (DCog) is utilised to investigate how theatre teams use surgical checklists as a cognitive artefact to complete goals. Nemeth describes cognitive artefacts as tools such as schedules, display boards, lists, and worksheets used to share work as part of DCog in an environment.⁵¹ Cognitive artefacts that are used in hospital organisations are products of various work activities that are distributed in time and location.⁵¹ Utilising an established theoretical framework to study surgical checklists as cognitive artefacts in use provides a structured methodological and analytical approach. DCog focuses on advancing knowledge and understanding of human interactions at work by broadening awareness beyond individual users of the checklist, enabling a more integrated approach to surgical checklist initiatives. The goal of DCog is to describe how distributed units are coordinated by analysing the interactions between individuals, the representational media used, and the environment within which the activity takes place.⁵² Therefore, DCog can be applied as a theoretical framework to guide data collection and analysis of surgical checklist use in practice.

1.4 Research Aims

The overall aim of this research is to investigate the use of surgical checklists by theatre teams in the operating theatre through two empirical studies. The findings of this research aim to contribute an evidence base and novel insight into understanding how existing surgical checklists are used in practice in UK hospitals. The research findings aim to inform redesign opportunities for existing surgical checklist use and propose recommendations to inform the future adoption of surgical checklists.

1.5 Research Questions

This research investigates the following overarching research question:

How do theatre teams currently use surgical checklists in practice?

In order to address this question, three research questions were defined and are investigated in the current research.

RQ1: What methodologies are applied to investigate how surgical checklists are used in practice, and what are the associated outcome measures?

RQ2: What is the current level of compliance to the WHO SSC in UK hospital operating theatres practice?

RQ3: How do theatre teams use a surgical checklist to prepare the operating theatre for hip arthroscopy surgery?

1.6 Research Scope

The scope of this research covers two surgical checklists used in surgery within UK hospitals. More specifically, this research investigates the use of one formal surgical checklist imposed at a national level and an informal surgical checklist provided at a local level. Surgical checklists as cognitive artefacts are the primary focus, mainly because they have been formally in use for over a decade, and there continues to be significant interest in understanding their strengths and deficiencies. Specifically, there is strong debate on the use of checklists in surgery and how they impact patient safety improvements.

Surgical checklists are used by theatre team members to perform their individual and collective tasks, contributing to shared goals and the overall

surgical process. Within the surgical process, the surgical procedure is considered the core activity in the operating theatre. The technical steps are highly standardised and defined by evidence-based medicine, which is well documented. In addition, healthcare professions are highly trained in technical competencies within their domain. This research will neither comment on nor attempt to modify the technical steps, although these are considered as part of the integrated process whereby surgical checklists are expected to be embedded, which may impact the flow of these technical steps. A systems approach will be taken, i.e. a focus on everything external to the surgical procedure, contributing to and supporting the technical steps, such as the theatre team behaviours when conducting their roles and responsibilities, the environment (i.e. the operating theatre), the tools used, etc.

The research utilised direct observations of two types of surgical checklists used in practice. The research is divided into two empirical studies, both contributing to and complimentary to the research aims and area of study. Empirical Study I adopts a quantitative approach to capture WAD; direct observation was conducted of a known and mandatory surgical checklist in use, i.e. the WHO SSC, which was observed across several surgical specialties. Empirical Study I provides an insight into surgical checklist adherence in UK hospitals to establish how a mandatory surgical checklist is used in practice, specifically the attempts made to perform the checklist and the quality of performance. Expanding on these findings, *Empirical Study II* adopts a qualitative approach to capture WAD by utilising an established theoretical framework to guide the methodological and analytical approach. This approach is applied to investigate how an unofficial surgical checklist is used in practice by theatre team members to prepare the operating theatre.

Two types of checklists have been selected to ensure a comprehensive investigation into both an official and an unofficial surgical checklist and how they are used by theatre teams in UK hospitals. Focusing investigations only on a well-known and frequently used surgical checklist has the potential to limit understanding of how surgical checklists are used in practice because its use is mandatory and therefore enforced; other unofficial checklists are recognised

but very rarely investigated. In Empirical Study I, the WHO SSC is targeted for investigation as a formal and globally used surgical checklist. In *Empirical Study II*, an unofficial locally produced surgical checklist is targeted for investigation. This surgical checklist is specifically used in hip arthroscopy surgery, which is an elective lower limb orthopaedic surgery. Hip arthroscopy is one of the newest techniques in orthopaedic surgery and is therefore considered a unique area for investigation due to its relatively new processes. The aim of selecting these two types of surgical checklists for investigation is to identify themes in how they are used, in order to highlight similarities, differences, and areas for improvement for surgical checklist use.

1.7 Key Benefits of this Research

This research will provide quantitative and qualitative evidence of how existing surgical checklists are used by theatre team members in UK hospitals. By interpreting real-world evidence, the findings of this research will contribute to further understanding of how surgical checklists are used and exemplify how applying a guiding theoretical framework, DCOg, will contribute to advancing knowledge in this high-profile area of interest.

The findings will:

- provide evidence-based findings to strengthen the knowledge related to checklist use in surgical settings;
- identify the current state of knowledge and gaps for further research;
- identify limitations with this type of research to improve future work;
- propose recommendations to inform redesign opportunities of existing surgical checklist use; and
- propose recommendations to inform the adoption of future surgical checklists.

In addition, the recommendations related to *Empirical Study II* will initially be applicable for use in hip arthroscopy surgery; however, these may be transferable for application to other surgical specialties.

1.8 Thesis Structure

The main thesis structure is presented below in *Figure 1-1: Flowchart of Thesis Structure*.

An overview of all the Chapters is presented in *Table 1-1: Thesis Structure and Chapter Overview* below.



Figure 1-1: Flowchart of Thesis Structure

Table 1-1: Thesis Structure and Chapter Overview

Chapter / Title	Chapter Overview
<p>Chapter 1: Introduction</p>	<p>Chapter 1 contains the following:</p> <ul style="list-style-type: none"> • An overview of the chapter. • An introduction to the research area with an explanation of why this topic is of interest and importance. • The research aims and scope; what specifically is being studied and in what context. • The benefits of this research for the advancement of knowledge and understanding, utilising a known theoretical framework.
<p>Chapter 2: Checklists: A Cognitive Artefact in High-Risk Industries</p>	<p>Chapter 2 contains the following:</p> <ul style="list-style-type: none"> • An overview of the chapter. • An introduction to checklists as a cognitive artefact from cognitive perspectives. • The introduction of checklists in high-risk industries and an explanation of how aviation became the pioneering industry for checklist use. • A brief introduction to the healthcare industry patient safety issues in surgery. • An overview of the introduction of surgical checklists as a patient safety improvement initiative.
<p>Chapter 3: Methods for Studying Surgical Checklist Use and Associated Outcomes: A Scoping Review</p>	<p>Chapter 3 contains the following:</p> <ul style="list-style-type: none"> • An overview of the chapter. • A scoping review of the methodologies and associated outcome measures to investigate surgical checklist use.

Table 1-1: Thesis Structure and Chapter Overview - Continued

Chapter / Title	Chapter Overview
<p>Chapter 4: Research Process</p>	<p>Chapter 4 contains the following:</p> <ul style="list-style-type: none"> • An overview of the chapter. • An overview of the research process: scoping review, research questions and objectives, applied methods, and research ethics. • Discussion of applicable methodological approaches. • Theoretical frameworks: introduction to Distributed Cognition (DCog) and Distributed Cognition for Teamwork (DiCoT) as guiding theoretical frameworks and a brief comparison with other theoretical frameworks concerned with understanding practice in working environments. • Rationale for selecting DCog and DiCoT as the most appropriate theoretical frameworks to apply to this research.
<p>Chapter 5: Empirical Study I: Direct Observation Study of the WHO Surgical Safety Checklist in use in UK Operating Theatres</p>	<p>Chapter 5 contains the following:</p> <ul style="list-style-type: none"> • An overview of the chapter. • An investigation into the real-world adherence to the WHO SSC in UK hospitals. • An understanding of surgical checklist use in practice as WAD for an evidence-based outcome.

Table 1 1: Thesis Structure and Chapter Overview - Continued

Chapter / Title	Chapter Overview
<p>Chapter 6: Empirical Study II: Distributed Cognition in the Operating Theatre</p>	<p>Chapter 6 contains the following:</p> <ul style="list-style-type: none"> • An overview of the chapter. • An investigation into how the operating theatre is prepared for surgery within the framework of DCog. • An introduction to hip arthroscopy surgery: understanding the joint cognitive system of the operating theatre utilising DCog and DiCoT. • An explanation of the qualitative methodological approach: observations, process mapping, freehand notes, and unstructured interviews.
<p>Chapter 7: Discussion and Conclusions</p>	<p>Chapter 7 contains the following:</p> <ul style="list-style-type: none"> • An overview of the chapter. • Key findings of this research. • A summary of contributions of this research. • Conclusions from the collective scoping review and empirical studies. • Limitations and suggestions for future work. • Suggested recommendations to inform the redesign of existing surgical checklists and the adoption of future surgical checklists.
<p>Chapter 8: Appendices</p>	<p>Chapter 8 contains the following:</p> <ul style="list-style-type: none"> • Appendices containing the supporting information for this research.
<p>Chapter 9: References</p>	<p>Chapter 9 contains the following:</p> <ul style="list-style-type: none"> • A full reference list of all citations contained within this thesis.

Chapter 2 Checklists: A Cognitive Artefact in High-Risk Industries

2.1 Overview of the Chapter

In this chapter the concept of checklists will be introduced with an overview of the different ways to view a checklist as proposed from cognitive theoretical perspectives. Checklists as a cognitive artefact will be explained with an overview of their adoption in high-risk industries as part of the joint cognitive system. An introduction to patient safety issues in the healthcare industry will be provided with a description of the adoption and evolution of surgical checklists.

2.2 Declarations

Librarian support: refining literature search strategies and training on EndNote X9 (citation manager).

2.3 Brief Overview of Checklists

2.3.1 Concept and Definitions

The concept of a *checklist* has existed for decades. It is a term used in everyday life and in professional work settings. In describing what a checklist is, numerous images and definitions are proposed depending on the theoretical stance and the context of its application. In its simplest form, the concept of a checklist is a list. A simple checklist may present itself as:

- a list of items to be checked or completed;⁵³
- a list of items to be remembered or actioned;
- a set of tasks or behaviours to be completed; or
- a way of recording the completion of steps in a structured and consistent manner.⁵⁴

Similarly, Hales et al describe a checklist as listed action items with a slightly more intricate view of the list containing systematically arranged criteria.⁵⁵ Simple checklists are typically used in daily life, although they are readily applied to capture basic work processes. From this simple concept applied in work settings, checklists evolved for use by human operators when machines advanced in their complexity and represented a memory aid to support the limitations of human cognition.⁵⁶

Checklists have been adopted by many industries, e.g. product manufacturing, packing facilities, and computing, although their application is most prevalent in safety critical industries. Checklists advanced in their concept to ensure the completion of safety critical steps and to reduce human error in complex high-risk environments.⁵⁷ In 1935, an accident involving a Boeing aircraft, prototype model 299, resulted in loss of life;⁵⁸ in response to this accident, the aviation checklist was born. This was a symbolic turning point in aviation from heavy reliance on the memory and skill of pilots to a life-threatening safety issue whereby pilots required support to perform their tasks. The tasks required to safely operate aircraft had grown in volume and complexity with the technological advancements, and the capabilities of the human were pushed

to new limits. A summary of this accident can be found in *Box 1 in Appendix A – Boeing Model 299 Accident Summary*.

Initially, aviation checklists were contained within the cockpit for pilot related tasks in order to safely operate the aircraft under normal conditions. The objective of these checklists was to ensure that the aircraft was correctly configured for each phase of flight, to enable the flight crew to cross-check actions, and to optimise flight crew coordination and workload.⁵⁹

Aviation is regarded as ultra-safe with its reputable evidence-based safety practices which draw on a multitude of validated techniques and tools, with the checklist being a tool that consistently demonstrates merit.⁶⁰ As a well-established high-risk industry, aviation has historically led the way in safety related aspects through lessons learned, transferring knowledge and experience of checklist use to other high-risk industries, such as rail, nuclear power, defence, and more recently in healthcare.

The figures below illustrate types of checklists spanning from a simple shopping checklist (*Figure 2-1: Simple Shopping Checklist*) to more complex types of checklist which can be found on a modern flight deck: a paper checklist (*Figure 2-2: Complex Paper-based Checklist⁶¹*) and a highly integrated electronic checklist (*Figure 2-3: Highly Integrated Electronic Checklist⁶²*).



Shopping List	
<input checked="" type="checkbox"/>
<input checked="" type="checkbox"/>
<input checked="" type="checkbox"/>
<input type="checkbox"/>
<input type="checkbox"/>

Figure 2-1: Simple Shopping Checklist

 NORMAL CHECKLIST		A319 A320 <small>November 2017</small>
BEFORE START		
COCKPIT PREP.....	COMPLETE (BOTH)	
GEAR PINS and COVERS.....	REMOVED	
SIGNS.....	ON / AUTO	
ADIRS.....	NAV	
FUEL QUANTITY.....	KG. / BALANCED	
TO DATA.....	SET	
BARO REF.....	SET	
WINDOWS / DOORS.....	CLOSED / ARMED (BOTH)	
BEACON.....	ON	
MOBILE PHONE.....	OFF (BOTH)	
THRUST LEVERS.....	IDLE	
PARKING BRAKE.....	SET	
APPROACH		
BRIEFING.....	CONFIRMED	
ECAM STATUS.....	CHECKED	
SEAT BELTS.....	ON	
BARO REF.....	SET	
MDA / DH.....	SET (BOTH)	
ENG MODE SEL.....	AS RQRD	
LANDING		
CABIN.....	SECURED FOR LANDING	
A / THR.....	SPEED / OFF	
GO-AROUND ALT.....	FT SET	
ECAM MEMO.....	LDG NO BLUE	
. I/G DOWN . SIGNS ON . SPLRS ARM . FLAPS SET		
PARKING		
APU BLEED.....	AS RQRD	
Y ELEC PUMP.....	OFF	
ENGINES.....	OFF	
SEAT BELTS.....	OFF	
EXT LT.....	AS RQRD	
FUEL PUMPS.....	OFF	
PARK BRK and CHOCKS.....	AS RQRD	
MOBILE PHONE.....	ON	
TRANSPONDER.....	STBY 2000	
RADAR / PWS.....	OFF	
Consider HEAVY RAIN EXTRACT.....OVRD		
AFTER START		
ANTI ICE.....	AS RQRD	
ECAM STATUS.....	CHECKED	
PITCH TRIM.....	% SET	
RUDDER TRIM.....	ZERO	
BEFORE TAKEOFF		
FLT CTL.....	CHECKED (BOTH)	
FLT INSTRUMENTS.....	CHECKED (BOTH)	
BRIEFING.....	CONFIRMED	
FLAPS SETTING.....	CONF (BOTH)	
FMA & TAKEOFF DATA.....	READ (PF) / CHECKED (PNF)	
TRANSPONDER.....	SET	
ECAM MEMO.....	TAKEOFF NO BLUE	
CABIN.....	SECURED FOR TAKEOFF	
ENG MODE SEL.....	AS RQRD	
TCAS.....	TA / RA	
PACKS.....	AS RQRD	
AFTER TAKEOFF		
LANDING GEAR.....	UP	
FLAPS.....	RETRACTED	
PACKS.....	ON	
BARO REF.....	STANDARD SET	
SECURING THE AIRCRAFT		
ADIRS.....	OFF	
OXYGEN.....	OFF	
APU BLEED.....	OFF	
EMER EXIT LT.....	OFF	
NO SMOKING.....	OFF	
APU AND BAT.....	OFF	
Consider COLD WEATHER		

FOR SIMULATION USE ONLY

Figure 2-2: Complex Paper-based Checklist



Figure 2-3: Highly Integrated Electronic Checklist

2.4 Checklists from a Cognitive Perspective

In order to fully comprehend the checklist as a tool to support human cognition, detailed explanation of multiple theoretical constructs is needed, which span cognitive psychology, cognitive sciences, Human Factors (HF), ergonomics, and cover other areas such as organisational culture, policies, and standardised practices. This section is not intended as an exhaustive account; it provides a broad overview, describing the development of checklists as a cognitive artefact.

The study of human cognition has enabled checklists to evolve as a cognitive artefact. An artefact is a tool with physical and perceptual properties designed for a specific purpose and typically utilised in a work setting.⁶³ Within the field of cognition, differing perspectives are proposed to understand the concept of a checklist, its interaction with other components, and its applications within various environmental contexts. The cognitive theoretical frameworks summarised below illustrate how these perspectives shifted the representation of the checklist when adopting the viewpoint of the unit of analysis. The traditional approach of viewing the checklist as being situated within the human mind shifted to an extended representation, thereby distributing the representation between the human operator and the checklist as an artefact outside of the human mind. This further shifted to a representation whereby cognition is distributed in the joint cognitive system.

Early cognitive psychology proposed the information processing approach, viewing information processing as an internal process whereby the representation of the checklist is internally situated within the human mind. This view was proposed from work which identified the constraints of human memory and limiting conditions such as forgetting.⁶⁴ In many situations in daily life, forgetting may have an insignificant impact, although in other situations forgetting may be critical. The limitations of the human mind were found to have detrimental impacts on the accuracy and speed of memory recall, which were later found to be alleviated by using a checklist.⁶⁵ This perception isolates

cognition within the confounds of the human mind and views checklists as a cognitive aid to support the functions of memory.

Engineering psychology proposed an alternative perspective, which was developed as a result of the impact of war. This shifted the need to move beyond understanding the human operator to understanding the man-machine system.⁶⁶ This view developed as part of the cognitive sciences movement with the advancement of technology used in World War II. This approach extended cognition beyond the confounds of the human mind to the man-machine interface whereby machines were viewed as artefacts with which man interacted. This view transformed the representation of a checklist to function as a support tool for improved cognitive abilities by way of standardising rules to create a cognitive aid.⁵⁵ The checklist as a cognitive artefact became necessary in situations when the demands on cognitive performance increased to a point that humans were unable to cope.⁵⁶

In the 1980s, HF engineering further developed the view of the checklist as a tool, with a focus on optimising human performance.⁶⁷ This work was paramount as the variability in human cognitive capabilities was recognised along with its impact on human performance at work. As technology continued to advance, the demands on humans increased. Humans as operators of technology had to manage operating tasks alongside conflicting aspects at work, such as distractions, fatigue, stress, and other competing cognitive and physical demands.⁵⁶ These aspects were found to have the risk of exposing humans to increased human error potential during task performance.^{68,69} de Vries et al explain that checklists contribute to decreased risk of human error by reducing the reliance on human memory and providing a platform of standardisation in working practices.⁷⁰ This work evolved the reputation of checklists as a simple memory aid to a tool capable of supporting users to improve other work-related skills such as enhancing shared situational awareness and decision-making. The checklist was designed for additional supporting functions such as engaging team members in active communication.⁷¹ These benefits have long been the focus of HF related domains and acknowledged by industries to support human performance in

work-related tasks. The use of checklists was found to formalise working practices beyond improvements in knowledge sharing and coordination to also contribute to rulemaking and training programmes.^{59,72-77}

A further shift in focus was proposed as the study of human cognition progressed in the theoretical framework of DCog. DCog extended cognition from the man-machine interface to distribute knowledge across the environment to the individuals, artefacts, and tools functioning within it.^{59,78} DCog was pioneered in the mid-1980s by Edwin Hutchins as a branch of cognitive science.⁷⁹ DCog is a theoretical and methodological framework to explain cognitive activities between team members within work settings.^{63,78,80} DCog is not focused on how individual tasks are broken down; Rogers explains that the focus of DCog is to understand how knowledge is conveyed between the members of a team via the propagation of information utilising artefacts and tools.⁸¹ Hutchins illustrated this view in his seminal studies: *Cognition in the Wild*⁵² and *How a Cockpit Remembers Its Speeds*.⁸² This work transformed the study of cognition from an artificial setting to the naturalistic study of humans at work. DCog was found to be a useful way to represent interactions between teams and their environment to achieve shared goals. In 1995, *Cognition in the Wild* showed how DCog was applied to investigate how a ship navigates. The study demonstrated how the task of navigation was conducted by a team working with various types of tools and described how information was propagated through the activity system by representational states to achieve a navigational fix. In the follow-on study *How a Cockpit Remembers Its Speeds*, Hutchins investigated an airline cockpit as a distributed cognitive system proposing that complex interactions take place between pilots and representational media within the cockpit. This study illustrated that cognitive properties are dependent on physical properties for a cockpit to remember its speed. Harris also discussed cognition and complex interactions, commenting that to understand human memory, it is necessary to consider functions outside of the individual.⁸³ The distribution of cognition among flight crew in the cockpit was further analysed by Hutchins and Klausen suggesting that these interactions can occur on two levels:

information is propagated and processed at one level, and cognition is shared at another level within a system of activity.⁷⁸

These studies represented how DCog can be applied to team coordination and cooperation in complex work settings, creating a foundation for studying the joint cognitive system of teams working in their environment. Operating theatres are complex working environments with multiple team members, assuming the role of actors in the joint cognitive system, each with a part to play. Combined, actors have shared goals which are achieved by the success of individual goals. Various aspects of the environment can be utilised as a representational state of knowledge to achieve these goals. The application of DCog aids in understanding cognitive artefacts as one representational state utilised by actors and how this plays a part in achieving shared goals.

2.4.1 The Joint Cognitive System

After several decades of research, cognition is now proposed to transpire in larger systems to form a joint cognitive system. In order to understand a joint cognitive system, the environment must be viewed as a whole. Within this whole is a complex range of interactions between people, artefacts, and tools. All must act together for the whole to function.⁸⁴ This work has mostly been applied to technology improvements whereby the redistribution of knowledge from humans to technology has benefited the working environment. More recent applications have been utilised in complex working environments to understand the inner complexities of a wider spread of interactions. These interactions occur between various parts of the system, comprising of the individual, the checklist, and influences from the socio-technical system.

Figure 2-4: An Illustration of the Socio-technical System⁸⁵ below simplifies this approach.

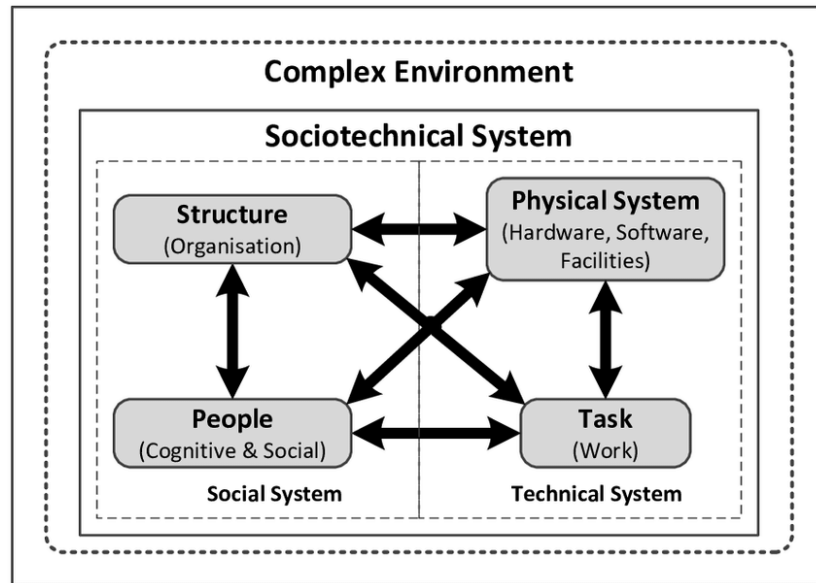


Figure 2-4: An Illustration of the Socio-technical System

Hollnagel proposed this approach as informing the design of technological systems by shifting the focus from internal functions associated with both the human operator and the machine, to external functions of the joint cognitive system which encompasses the environmental context.⁸⁶ As the complexities of working environments increased to encompass external influences, this view became more realistic as boundaries expanded. The aviation industry functions as an example of a highly complex system. Hollnagel depicts the relative boundaries in aviation, as shown in *Figure 2-5: Relative Boundaries for the Joint Cognitive System*⁸⁶ below.

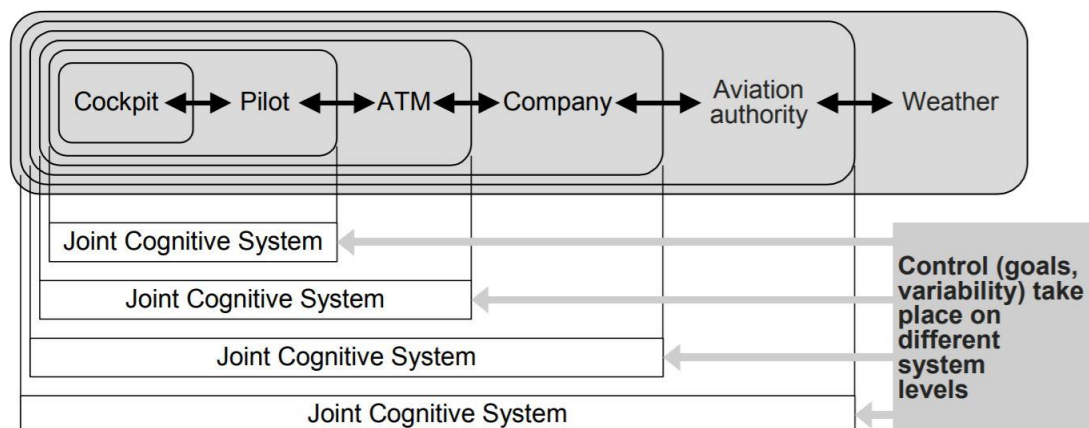


Figure 2-5: Relative Boundaries for the Joint Cognitive System

Within this system, aviation has evolved to fully embed checklists throughout the industry, and they function as part of the joint cognitive system. Checklists are primarily used for standardisation of working practices and have been implemented into all areas of the industry such as aircraft manufacturing, airline operations, and aircraft maintenance. They are heavily mandated and considered common practice throughout the industry. Extensive research continues to focus on design considerations, development, and implementation of checklists. Other high-risk industries continue to exemplify methods for the effective use and application of checklists through understanding their strengths and weaknesses. Over the decades, outstanding findings have supported the benefits of checklists in bringing structure to work processes, providing shared mental models and improved communication in team performance, accountability, and safety culture.⁸⁷⁻⁸⁹ However, work in this area has also exposed issues related to checklist design, implementation, and sustainability. As with any tool applied to working environments, the issues are multifaceted.

Within high-risk industries, checklists continue to play an integral role in error management as a safety tool, and they are under rigorous control.^{55,90,91} Reliance on checklists as a significant tool in error management is found to improve performance, reduce costly errors, and benefit overall outcomes.⁵⁵ Checklists have been hailed as powerful tools and a go-to solution for safety improvements. Their existence continues to be endorsed and empowered, which has seen the adoption of surgical safety checklists in healthcare to improve patient safety.^{10,92-95}

2.5 Introduction to Patient Safety

An overview of healthcare patient safety is provided in this section to support understanding of the issues related to the research area, why checklist use in surgery was initiated, and why it continues to be a pertinent topic.

In the UK there are several organisations that have an impact on policies, procedures, and practices in UK medical institutions. The National Health

Service (NHS) was established after the Second World War to deliver healthcare in the UK. Within the UK the four countries: England, Northern Ireland, Scotland, and Wales have their own separately financed NHS,⁹⁶ and therefore, NHS England is responsible for healthcare in England.⁹⁷ The World Health Organization (WHO) was established in 1948 with the role to direct international health in the United Nations. The WHO works internationally with its head office in Geneva, Switzerland.⁹⁸ *The Joint Commission on Accreditation of Healthcare Organizations* (JCAHO) was established in 1951 as an independent and not-for-profit organisation.⁹⁹ The JCAHO is responsible for the accreditation and certification of American healthcare organisations and programmes, and it is committed to the establishment of standards and protocols to ensure quality and performance standards. Although the organisation is primarily for the United States of America and Canada, it has also had an impact on the UK. The JCAHO collaborates with the WHO to ensure that standards are disseminated globally across healthcare institutions. These healthcare organisations collaborate to ensure that safe and consistent healthcare is delivered within the UK. Each has a role to play in the development, implementation, and sustainability of improved patient safety improvement.

Patient safety issues are not new. In 1956, a paper in the *New England Journal of Medicine* raised the concept of medical errors and their contribution to medical progress.¹⁰⁰ From the late 1990s, seminal reports emerged to present healthcare as a high-risk industry with pertinent patient safety issues, specifically representing a significant issue of high rates of adverse events. Healthcare by its very nature is high-risk because it deals with people requiring medical treatment. In the key reports: the *Institute of Medicine* (IoM) '*To Err is Human: Building a safer Health System*',² the Department of Health (DoH) '*An organisation with a memory*',¹¹ and the IoM '*Crossing the quality chasm*',¹⁰¹ the risks of high error rates were reported to be particularly prevalent in surgery.¹⁰²

It has been estimated that approximately 234.2 million major surgical operations are performed yearly.¹⁰³ Such figures have led the healthcare

industry to focus on the management of preventable patient harm. In addition to the impact on patients, high numbers of preventable medical errors have been found to result in increased patient safety costs, both in terms of a significant financial impact and the industry's reputation.^{104,105} Thus, the healthcare industry responded to these alarming figures by launching industry-wide patient safety improvement initiatives.

In their early concept, the primary aim of patient safety initiatives was to combat some of the reported issues by improving standardisation and clinical patient safety outcomes.¹⁰⁶ However, this was not an easily achievable aim as surgery covers a wide range of surgical specialties with added variability related to the patient's medical condition. Globally, surgical procedures are relatively standardised by the technical processes governed by the policy makers and statutory bodies, along with third party organisation contributions.

Spanning the last two decades, agencies and research institutions have made a significant contribution to knowledge by identifying variable aspects of practice that can be standardised to improve patient safety. An area profoundly covered in the patient safety literature is theatre team performance and associated non-technical skills, i.e. leadership, communication, coordination, decision-making etc.¹⁰⁷⁻¹¹¹

A combination of technical and non-technical skills determines overall team performance, yet in surgery theatre team performance has received high-profile coverage highlighting areas where substandard team behaviours and working practices may negatively impact patient safety.¹¹²⁻¹¹⁴ As understanding evolved, the patient safety improvement movement began to focus initiatives on theatre team performance aspects in surgical settings.

Research addressing issues related to non-technical skills has explained them as mostly due to economic and safety culture differences.¹¹⁵⁻¹¹⁷ The global spread of healthcare likely determines the variance across countries, which has been suggested to be amplified by local variances residing within individual healthcare institutions. McCulloch et al add other variances as

possible contributors to non-technical skills related issues such as training programmes and a range of attitudes within the surgical team.¹¹⁷

Therefore, theatre team performance issues were found to be multifaceted, and combating such a complex combination of issues was a significant undertaking. The healthcare industry considered common approaches used in other high-risk industries following a recommendation to implement checklists into medical practice as a verification process.² Provonost and Gawande pioneered a shift to implement checklists into surgical processes.^{92,93,118}

The operating theatre is a complex joint cognitive system, and the introduction of surgical checklists imposes further changes to the system. The joint cognitive system represents multiple components of the system with complex internal and external interactions. *Figure 2-6: Proposed Joint Cognitive System in Healthcare*¹¹⁹ below illustrates a proposal of the multiple layers.

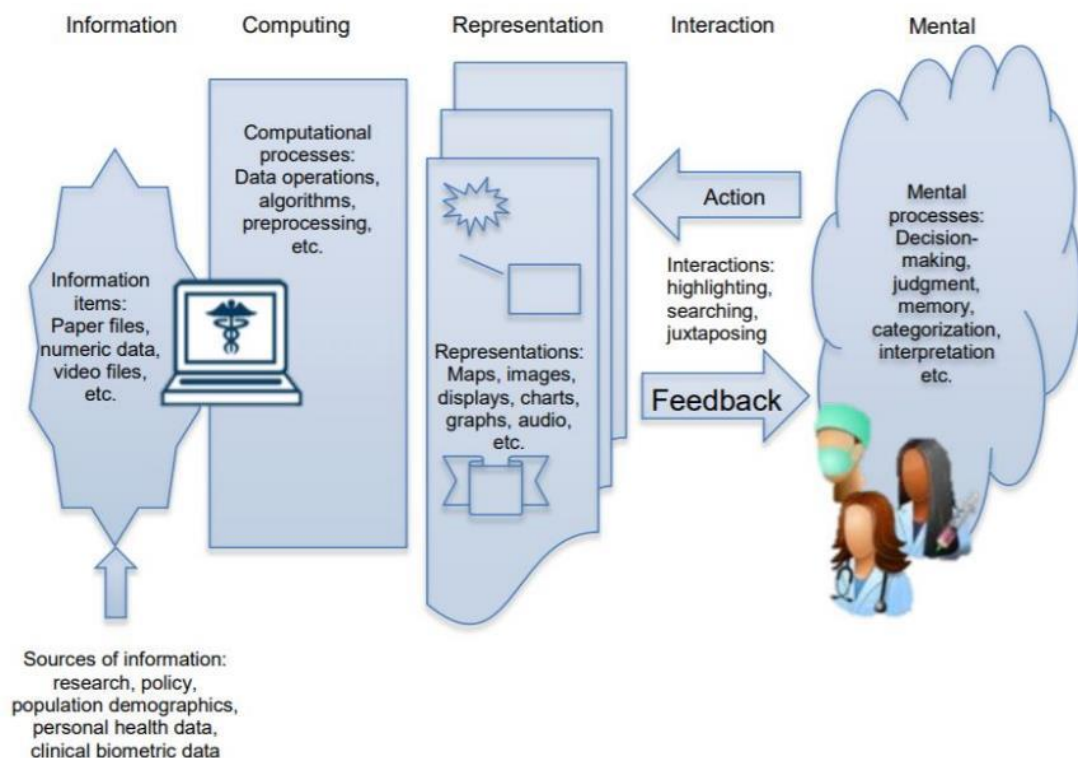


Figure 2-6: Proposed Joint Cognitive System in Healthcare

The operating theatre is described by Woods and Hollnagel as a system governed by the policies and procedures of the organisation, influenced by constraints, and shaped by the individuals within the system.⁶³ Surgical procedures are rooted in evidence-based practice and executed via policies and guidelines. The workings of the joint cognitive system can be viewed as “the blunt end” which is reliant on interdependencies between the various components of a complex system.¹²⁰ The adoption of surgical checklists can be investigated by considering how the checklist is used as a cognitive artefact within the joint cognitive system of the operating theatre.

2.6 The Adoption of Checklists in Surgery

In 2003, the *Keystone Intensive Care Unit (ICU) Project*¹²¹ pioneered the introduction of checklists into surgical settings in a quality improvement effort. The project was led by members of the *Michigan Health Association* in collaboration with the *Quality and Safety Research Group (John Hopkins University)*.

The objective of the project was ultimately to improve the safety culture within hospitals by designing a checklist to reduce bloodstream infections from central lines.¹²¹ The surgical checklist was implemented into 108 ICUs across 77 hospitals. Almost two years after implementation, the intervention reported successful results, showing that the median rate of Central Line-associated Blood Stream Infection (CLABSI) was down to zero, and safety culture had improved by more than 50%, with additional results of compliance with ventilator care reaching 99%.¹²¹ The conclusions of this project raised awareness related to the benefits of surgical checklists, creating an evidence-base for surgical checklists to be developed as part of patient safety initiatives.

Following the *Keystone ICU Project*, the time-out checklist was introduced and later mandated by the JCAHO as a Universal Protocol. The Universal Protocol was established for the prevention of wrong-site, wrong-side, wrong-procedure, and wrong-person surgery.¹²² The universal protocol contains

three stages, all designed to be performed prior to the start of the surgical procedure.

Stage 1 is referred to as preoperative verification. This stage is designed to verbally confirm the correct patient and other important information such as the correct procedure and operative site. In addition, relevant documentation is checked at this stage.

Stage 2 is marking of the operative site. This involves drawing an agreed and recognised symbol on the patient's operative site with a marker pen.

Stage 3 is referred to as a time-out. The time-out is intended as an opportunity for the theatre team to pause before the surgical procedure commences. This is an opportunity for the team to actively communicate critical information to re-confirm: (a) that they are about to operate on the correct patient, (b) that the correct operative site has been marked in stage 2, and (c) a final confirmation that the correct procedure is about to be performed. The time-out is performed before an incision is made on the patient's operative site.

The time-out proved successful and created an evidence-based foundation for future surgical checklist interventions. Following these successes and in response to the earlier published reports^{2,11,101} indicating that surgery was unsafe, the WHO launched a campaign in January 2007 called '*Safe Surgery Saves Lives*'.¹²³ This campaign was part of the ongoing efforts to improve patient safety.

The WHO campaign members of the *Safe Surgery Saves Lives* study group introduced a perioperative checklist intervention referred to as the *WHO Surgical Safety Checklist (SSC)*.^{1,10} The perioperative checklist contains 19 items designed to facilitate the improvement of teamwork in the operating room between theatre team members. The overall aim of the checklist was to ensure consistency in applying safety processes. Haynes et al add that the program was hypothesised to improve surgery by decreasing surgical complications and ultimately loss of life.¹

The WHO backed the high-profile initiative and succeeded to recruit eight hospitals to participate. Hayes et al explain that selecting hospitals from a range of countries ensured participation of diverse population groups and representation of economic variance.¹ The following countries participated in the study: Toronto, Canada; New Delhi, India; Amman, Jordan; Auckland, New Zealand; Manila, Philippines; Ifakara, Tanzania; London, England; and Seattle, Washington.

The WHO SSC was designed with multiple considerations. The study group learnt from the success of the *Keystone ICU Project* using the design of the checklist and implementation as an evidence base.^{55,118,121,124} The 19 items were defined based on the content of the Universal Protocol time-out and the WHO guidelines which identified safety practices for surgical patients.^{1,10} The first edition of the WHO SSC can be found in *Appendix B – WHO Surgical Safety Checklist*.

The WHO SSC is designed as one complete checklist consisting of 3 sections which are intended to be performed sequentially at specific times within the surgical flow:

1. Section 1 'sign-in': the sign-in section of the WHO SSC is aimed to check if the correct patient is present for surgery, to confirm the procedure, and to confirm that bloods are available. All these checks are prior to anaesthetic administration.
2. Section 2 'time-out': the time-out section is aimed to re-check that the correct patient is present for surgery, to confirm the procedure, mark and confirm the correct surgical location, and confirm if any special equipment is needed and available. All these checks are prior to the first incision.
3. Section 3 'sign-out': the sign-out section is aimed to confirm that the surgical procedure was completed with no complications and to confirm that all equipment was accounted for. In addition, any special post-surgical treatment is specified at this time. All these checks are post-surgical procedure, after closure of the surgical wound.

During the global implementation of the WHO SSC, the following factors were considered:¹

- the checklist was translated into relevant languages for the participating hospitals;
- it was adjusted to fit into the flow of care at each institution;
- a co-investigator was based at each participating site to lead the intervention with hospital administration support;
- a local data collector was selected and based at each site and trained by the study team on the identification and reporting of process measures and complications;
- theatre teams were introduced to the WHO SSC via lectures, written materials, or direct guidance by the researcher;
- the period of introduction of the checklist ranged from 1 week to 1 month.

During step one of the two-step implementation programme, the baseline data collection phase identified areas of deficiencies related to required changes in systems and surgical team behaviours. The nineteen item checklist was implemented to improve practices within these institutions through identifying safety critical items to include in the checklist. Flow of care adjustment needs in each of the participating hospitals were not detailed. Overall, the focus of flow of care adjustments was primarily related to timings to ensure that the WHO SSC sections were able to fit into natural pause points within the surgical flow. An additional flow of care change was related to the administration of antibiotics. Originally, administration of antibiotics was conducted in the pre-operative wards; recorded frequent delays highlighted the need for a change to administer antibiotics in the operating theatre.

The WHO emphasise adaptation of the WHO SSC to local needs. Ethnography research highlighted that the time-out section was often adapted to meet the demands of the operating theatre environment; adaptations include modifications to the content, the timing of administration of the checklist sections, and the number of theatre team members involved.¹²⁵

Further considerations related to flow of care adjustments are provided in support material from the WHO: *The WHO Surgical Safety Checklist: Adaptation guide*.¹²⁶ The guide highlights seven areas to focus adjustments, summarised as follows:

1. Focused: the checklist must remain concise and contain only critical items. The number of items in each section must be kept to a minimum.
2. Brief: each checklist section must take no longer than one minute to complete.
3. Actionable: all items must be linked to a specific, unambiguous action.
4. Verbal: continue to ensure that each item can be read aloud to avoid written communication.
5. Collaborative: modifications must be made through collaboration with representatives of individuals who may be involved in using the checklist.
6. Tested: any modification must be tested prior to rollout.
7. Integrated: it is important to combine pre-existing safety processes / checklists with the WHO SSC.

The primary outcome measures for the WHO SSC was occurrence of any major complication including death within a period covering postoperative hospitalisation for up to 30 days. Haynes et al detail the results to show that after the WHO SSC was introduced, the rate of death declined to 0.8% from 1.5% ($P=0.003$), and inpatient complications declined to 7.0% from 11.0% ($P<0.001$).¹

In reporting these successful results, the WHO SSC was acclaimed to have positive impacts to patient safety improvements. The WHO SSC continues to be governed by the WHO for mandatory use and remains one of the most globally widespread used surgical checklist.^{1,92,127} However, in contrast, the WHO SSC is also one of the most extensively debated surgical checklists across the world. The WHO SSC is supported as a preventative measure for patient safety issues; however, there is doubt that the WHO SSC alone can have such a significant impact on patient safety improvements.

There is a large amount of evidence for the support of checklist use in other safety critical industries.^{48,55,72} Checklists are embedded throughout the safety processes of these industries; a number of factors are considered in their design and implementation to ensure that checklists are fully embedded, such as the organisational culture, training, procedures, and adherence auditing.

A decade since implementation of the WHO SSC, attention has turned to whether the checklist is being used as intended with many studies focusing on compliance and adherence issues. Users' perceptions and acceptance of the WHO SSC use have also been studied. The WHO SSC is being applied to other areas of healthcare such as anaesthesia; see *Appendix C – WHO Anaesthesia Checklist*.¹²⁸ Early interventions with reported positive outcomes allowed for recognition of surgical checklists and their associated benefits, launching a new era of their use in surgical settings. Healthcare governing bodies continue to support several checklists in an official capacity. These surgical checklists can either be imposed via mandatory use or endorsed and encouraged.

Chapter 3 Methods for Studying Surgical Checklist Use and Associated Outcomes: A Scoping Review

3.1 Overview of the Chapter

In this chapter, the scoping review approach will be introduced. The methodologies applied to investigate surgical checklist use in the operating theatre will be identified, with an account of the associated outcome measures. In learning from the work of others, gaps in the literature will be highlighted to identify potential areas for improvement, thereby defining the motivation for this research.

3.2 Declarations

Academic librarian support for scoping review methodology validation and literature search strategy support.

3.3 Background to the Selected Research Area

An explanation of how the research area was identified from my involvement in the S3 Project and my professional experience is provided in *Chapter 4: Research Process*. From this experience, I accumulated a preliminary set of literature related to checklists. This literature included the transfer of knowledge from aviation checklists to checklist use in surgical settings, a collection of seminal reports from the healthcare industry, and work related to patient safety improvement initiatives.

Within the last decade, the adoption of surgical checklists has received extensive focus, and there is an ongoing active debate surrounding their use in surgery. Many aspects related to surgical checklists could have been selected to study, spanning their concept, design, implementation, and sustainability in surgical settings. However, the selected research area was refined in scope to *checklist use in surgery*. Investigating this area can fall under multiple areas of study, for example, 'healthcare initiatives', 'patient safety improvements', 'surgical checklist interventions', 'surgical safety checklists' etc.

The preliminary literature provided identification of seminal work and key authors active in the research area. Since implementation of the WHO SSC, an extensive body of work has applied quantitative, qualitative, and mixed methods to the investigation of surgical checklists. All are pertinent to the investigation of surgical checklists; however, no standardised approach was identified. Therefore, the research aim was to investigate the use of surgical checklists by theatre teams in the operating theatre to establish and understand how existing surgical checklists are used in current practice in UK hospitals.

To comprehensively address this aim, numerous methodological approaches to review the literature could have been taken. In assessing the various methodologies, the strengths and weaknesses of each were evaluated in the context of this research aim. Firstly, the option to conduct a systematic review

was considered as this is commonly used in clinical research. Following the PICO method, it was determined that a systematic review was a relatively restrictive methodology for this research. This approach would have narrowed the search to quantitative approaches and eliminated the qualitative literature. Systematic reviews are best suited to compare the impact of well-defined interventions investigating specific outcomes. In addition, this highlighted that numerous studies had been conducted with a focus on the WHO SSC and clinical outcome measures, which restricted the investigation of other surgical checklists and varied outcome measures. Therefore, early investigation highlighted that literature related to checklist use in surgery was significantly focused on the successes and pitfalls associated with the use of the WHO SSC. As I was aware of multiple surgical checklists and the breadth of work, I researched methodologies that would encompass the mixed methods of both quantitative and qualitative studies. Due to the significant contribution of qualitative studies in this area of research, I investigated the options to conduct an integrative review and meta-ethnography. Both have strengths in considering qualitative work, although they limit consideration of quantitative work and other sources.¹²⁹

The preliminary literature provided some evidence related to the investigation of surgical checklist use. However, it was unclear to what extent the practice of surgical checklist use had been investigated. A scoping review was justified to map the methodologies used to investigate surgical checklist use and the associated outcome measures. Scoping reviews are often used in early identification of research gaps.¹²⁹

3.4 Approach to the Scoping Review

The aim of the scoping review was to provide a broad overview of important concepts and types of evidence in this research area. To identify key concepts, a summary of the literature was adequate. Synthesising the literature allows for evaluation of the quality of the evidence; however, this was not necessary for this research aim. The scoping review considered a wide range of study designs; therefore, the quality characteristics of existing research was not an

exclusion criterion. To strengthen the quality of this scoping review, methodological guidelines were followed as proposed by Arksey and O'Malley.¹³⁰ Additional material was utilised for the scoping review guidance, such as methodology refinements proposed by Levac et al¹³¹ and a range of scoping reviews and scoping review protocols.^{132,133}

The scoping review methodology consists of five stages:

1. identifying the research question
2. identifying the relevant literature
3. study selection
4. charting the data
5. collating, summarising, and reporting the results.

The scoping review was conducted in an iterative process. Firstly, the research question was defined, then an initial scoping review was conducted at the beginning of the research period to gain knowledge of existing studies and indicate research gaps. The first scoping review supported definition of the empirical study approach in this research. It was necessary to update the scoping review to account for the continuing influx of new studies during the research period.

3.4.1 Methods and Analysis

This section details the methods and analysis process followed in this scoping review. Each of the five stages are explained below.

3.4.1.1 Stage 1: Identification of the Research Question

Review of the preliminary literature identified that the research area was rapidly growing with numerous studies investigating surgical checklist use, which illustrated a need to advance knowledge. Early review did not provide a clear indication of the ways in which surgical checklists were used in practice, as research focused more on post-surgical checklist implementation issues

and impacts of surgical checklist use. None of the identified early research clearly addressed surgical checklist use as WAD; therefore, the scoping review addressed the following research question to establish the current state of knowledge:

RQ1: What methodologies are applied to investigate how surgical checklists are used in practice, and what are the associated outcome measures?

3.4.1.2 Stage 2: Identification of the Relevant Literature

The literature search strategy was developed with guidance from two academic librarians who specialised in searching for literature related to clinical research. Firstly, a review of the preliminary literature was performed. The method of snowballing was applied to the preliminary set of literature. Specifically, backwards snowballing was applied whereby the reference lists of key papers were reviewed, which expanded the preliminary literature by identifying papers that were frequently cited in the research area. The preliminary literature was sorted into categories. The categories were defined by personal experience and judgement of topics within the research area. Categories included: 'protocols', 'guidelines', 'World Health Organization Surgical Safety Checklist', 'surgical checklists', 'checklist use in surgery', 'surgical checklists for clinical improvements', 'surgical checklist barriers and facilitators' and 'surgical checklist compliance.' In addition, any authors' work which was recommended by research associates and supervisors was reviewed for relevance including books, white papers, and newspaper articles. These were added to the relevant category, as required. Other sources were searched to ensure coverage of all relevant literature, i.e. healthcare related organisation websites, such as reports from the WHO and policy documents from the *National Institute for Health and Care Excellence* (NICE) guidelines. This search did not identify any relevant studies for inclusion in the scoping review.

Appropriate databases to search the literature were then selected. To ensure identification of appropriate databases, the academic librarians confirmed the

order of searching within the following databases: PubMed, Web of Science, and Scopus followed by a final search on Google Scholar.

To ensure that the included studies were relevant, the Population (P), Context (C), and Concept (C)^{131,133} were defined as the following:

- Population (P): core theatre team members working in a hospital operating theatre;
- Context (C): the setting is surgical checklist use in a hospital operating theatre; the specific phase in the surgical process flow is from the theatre team preparing the operating theatre for surgery to when the patient leaves the operating theatre; and
- Concept (C): use of a surgical checklist.

In order to start the scoping process for relevant literature, Medical Subject Heading (MeSH) and keywords were identified from the initial set of papers. The term 'checklist' was determined to be too general. The term 'surgical checklist' was identified as formally being introduced as a major MeSH heading in 2010; however, the search strategy was defined from 2008. The search terms were selected with consideration to generate word strings related to the research area using controlled vocabulary. The following search terms were combined through Boolean AND, and OR within each search term respectively: 'healthcare initiatives', 'patient safety improvements', 'surgical checklist interventions', 'surgical checklists', 'checklist use in surgery', 'checklists in the operating room', 'surgical safety checklists', 'World Health Organization (WHO) Surgical Safety Checklist', 'surgical checklist design', 'surgical checklist implementation', 'surgical checklist compliance / adherence', 'surgical checklist benefits', 'surgical checklist issues', 'surgical checklist barriers and facilitators' and 'orthopaedic surgical checklists.'

All literature selected for inclusion was managed within the EndNote X9 citation manager software (desktop version).

3.4.1.3 Stage 3: Study Selection

The selection of relevant studies was conducted in a systematic manner utilising the PRISMA flowchart for reporting,¹³⁴ which was adapted to meet the needs of the scoping review. The database searches generated various types of literature. To aid the limitation of single researcher bias during the selection of relevant studies and to support the selection of literature, inclusion and exclusion criteria were defined; these were verified by the academic librarian for adequate content, detailed below in *Table 3-1: Inclusion and Exclusion Criteria*. Ideally, this process would have been conducted by at least two researchers. However, I solely performed all literature screening utilising experienced judgement. Only papers meeting inclusion criteria were selected.

Table 3-1: Inclusion and Exclusion Criteria

Inclusion	Exclusion
Publication date 2008 (inclusive)-present.	No version available in the English language.
Titles and abstracts in the English language.	Abstract insufficient to determine if a method and / or outcome measure was applied.
Studies from any geographical location.	Other high-risk industries (i.e. aviation, nuclear).
Surgery performed in an operating theatre at general hospitals.	Non-surgical checklists.
Patients are human.	Surgical checklist as part of a bundle when it is unclear if they are used in an operating theatre setting.
Surgery performed on adults and children.	Any surgery performed in a non-hospital setting i.e. in clinics, military battlefield, hospice, home, or rehabilitation centre.
Any surgical specialty performed in a hospital setting.	Types of surgical specialties performed in a non-hospital setting i.e. dental surgery.
Official / mandated / endorsed surgical checklist.	Studies that include animals.

Table 3 1: Inclusion and Exclusion Criteria - Continued

Inclusion	Exclusion
Unofficial / informal surgical checklist.	Special permission required / not available to the public i.e. military study classified restricted or above.
Studies using quantitative methods.	Non-empirical opinion pieces.
Studies using qualitative methods.	
Pilot / trial studies.	

An initial review of titles and abstracts enabled identification of literature to be included and literature to be excluded. On occasion whereby the content was not clear from the title or the abstract, the full paper was reviewed. The results of this review are presented below in *Figure 3-1: PRISMA Flow Diagram*.

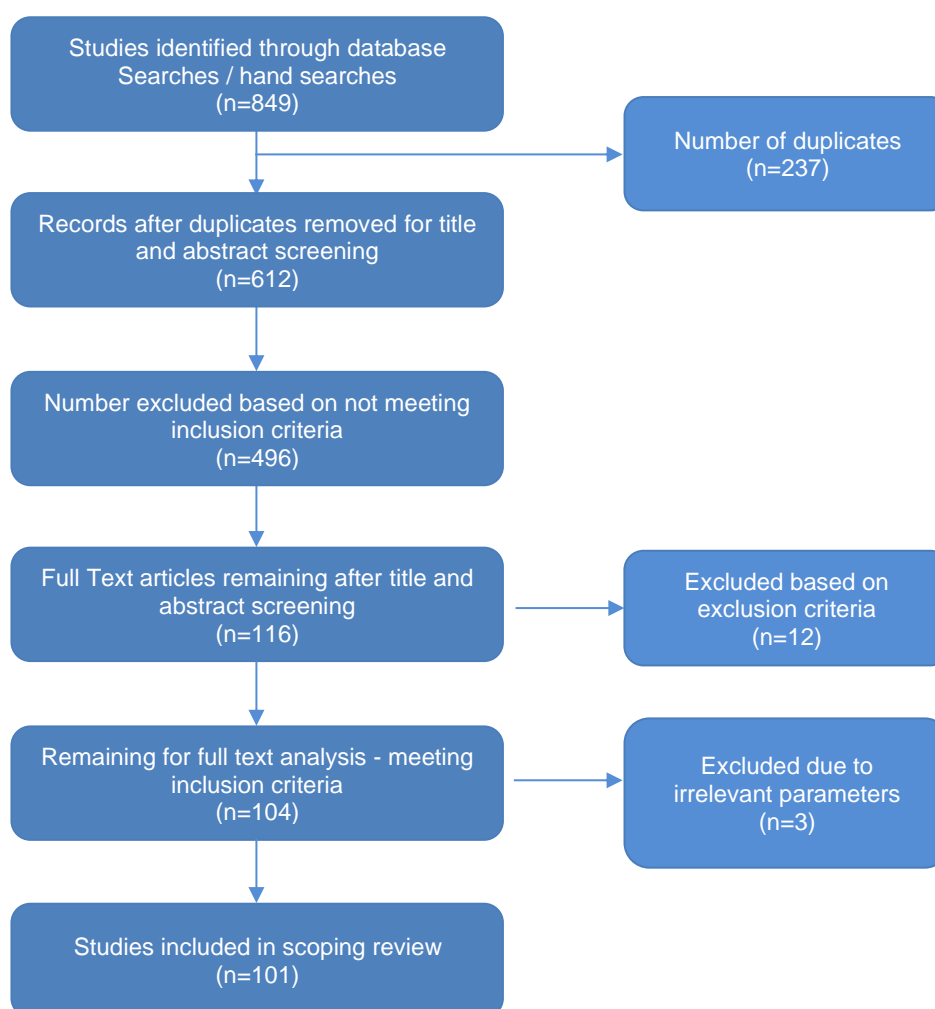


Figure 3-1: PRISMA Flow Diagram

The scoping review strategy was employed to ensure coverage of concepts related to surgical checklists. Therefore, evaluation of the quality of the included research is limited by a lack of comparison of methods, outcome measures etc. The first round of organising the literature involved identifying primary and secondary research. Primary research was identified as new work in the research area, and secondary research was identified as work that summarised the current state of research.

3.4.1.4 Stage 4: Charting the Data

A data abstraction table was developed in the form of a concept matrix to support the charting of the data. The concept matrix was designed to include categories relevant to understanding the key concepts related to investigating surgical checklist use. The selected data items include: (1) year of the study publication, (2) the study source by author and reference, (3) the methodological approach detailed in the study by categorisation, and (4) the outcome measure detailed in the study by categorisation. The concept matrix was trialled on five studies to ensure appropriate coverage of data. All studies selected for inclusion were used to populate the concept matrix. The aim of the scoping review was to map the methodologies and associated outcomes applied to investigate checklist use in surgery. Therefore, the content of the concept matrix was arranged in chronological order to aid in the identification of possible themes within the data.

An iterative scoping methodology was applied to ensure that the expanding body of literature was reviewed and up to date. The initial scoping strategy was conducted to incorporate the date range of 2008 to 2012; the scoping strategy was reapplied in 2019 to ensure that recent publications were included, when relevant. The concept matrix was used to generate summary tables: the first table was designed to summarise the methods applied to investigate surgical checklist use. The second table was designed to summarise the outcome measures when investigating surgical checklist use. Each of the tables were used to present the key concepts as categories with the associated number of studies. The third table was designed to present the

methods and outcome measures by year of the study. It was determined that evaluating the quality and level of evidence would not provide any additional information to benefit identification of the key concepts. Therefore, no further synthesising of data was conducted.

3.4.1.5 Stage 5: Collating, Summarising, and Reporting the Results

The scoping review aimed to provide an overview of the literature reviewed. The organisation of the concept matrix enabled analysis of the included literature for reporting by following two strategies: (1) a numerical analysis of the studies, i.e. the overall number of studies, the type of methodology applied, and the outcome measures; and (2) a brief thematic mapping of the studies, e.g. to identify any themes in the approaches to investigating surgical checklists. The scoping review identified several systematic reviews related to studies investigating surgical checklist use. Through analysis, the systematic reviews were found to summarise some of the previously selected studies; therefore, they were cross-referenced as validation for content accuracy.

3.4.2 Results

The scoping review search identified 849 articles; 237 duplicates were removed. The remaining 612 articles were reviewed for title and abstract content to meet the inclusion criteria. A further 496 were excluded as they did not meet the inclusion criteria. Adequate information was available in the majority of the abstracts; however, all 116 were selected for full text review of the methods and outcomes to ensure adequate information extraction. Of this total, 12 publications were excluded based on identification of opinion pieces and studies related to guidelines only. In addition, 3 publications were excluded as they did not have adequate information in the full text paper, i.e. non-specific parameters. The initial scoping review found 53 studies between 2008-2012. The second scoping review found an additional 48 studies between 2013-2019. The final total number of studies included was 101.

The concept matrix was populated with data from the 101 studies and can be found in *Appendix D – Scoping Review Concept Matrix*. Categorisation of the studies was relatively straightforward for methodological approaches. Often the study design was clearly stated, and the methods adopted required further investigation in the full text. However, reporting of outcome measure was extremely variable. This created difficulties with assigning studies to outcome measure categories. Exact representation of the outcome measures would have resulted in several additional categories; therefore, categories were defined based on themes which included one or more outcome measures. Each study was analysed for the methodological approach and the outcome measure; multiple categories were applicable for some of the studies.

The numerical analysis of the included studies provides the range of methods with the total number of identified studies. The summary table can be found below in *Table 3-2: Scoping Review Summary of Methods (2008-2019)*.

Table 3-2: Scoping Review Summary of Methods (2008-2019)

Methods	Total Studies	Study References
Observation – Quantitative	38	Schwendiman, ¹³⁵ Lacassie et al, ¹³⁶ Mayer et al ¹³⁷ Lepanluoma et al ¹³⁸ , Haugen et al ¹³⁹ Saturno et al ¹⁴⁰ , Urbach et al ¹⁴¹ , Ryan et al ¹⁴² Lubbeke et al, ¹⁴³ Pickering et al, ¹⁴⁴ Bliss et al, ¹⁴⁵ van Klei et al, ¹⁴⁶ Fourcade et al, ⁴⁵ Petrovic et al, ¹⁴⁷ Vogts et al, ¹⁴⁸ Sewell et al, ¹⁴⁹ Haynes et al, ¹ Calland et al, ¹⁵⁰ Lingard et al, ⁴⁷ Askarian et al, ¹⁵¹ Lyons, ¹⁵² Weiser et al, ¹⁵³ de Vries et al, ¹⁵⁴ de Vries et al, ¹⁵⁵ Papaspyros et al, ¹⁵⁶ Einav et al, ¹⁵⁷ Vats et al, ⁴³ Norton et al, ¹⁵⁸ Buzink et al, ¹⁵⁹ Thomassen et al, ¹⁶⁰ Harrop et al, ¹⁶¹ Haynes et al, ¹⁶² Henrickson et al, ¹⁶³ Johnston et al, ¹⁶⁴ de Vries et al, ¹⁵⁵ Lingard et al, ¹⁶⁵ Verdaasdonk et al, ¹⁶⁶ Rosenberg et al ¹⁶⁷
Observation – Qualitative	14	Schwendiman, ¹³⁵ Ziman et al, ¹⁶⁸ Sendlhofer et al, ¹⁶⁹ Rydenfält et al, ¹⁷⁰ Poon et al, ¹⁷¹ Sparks et al, ¹⁷² Hannam et al, ¹⁷³ Cullati et al, ¹⁷⁴ Braaf et al, ¹²⁵ Aveling et al, ¹⁷⁵ Levy et al, ¹⁷⁶ Sheena et al, ¹⁷⁷ Spence et al, ¹⁷⁸ Styer et al ¹⁷⁹
Questionnaire / Survey	22	Magill et al, ¹⁸⁰ Wong et al, ¹⁸¹ Kawano et al, ¹⁸² Cullati et al, ¹⁸³ Lepanluoma et al, ¹⁸⁴ McLaughlin et al, ¹⁸⁵ Haugen et al, ¹⁸⁶ Papaconstantinou et al, ¹⁸⁷ O'Connor et al, ¹⁸⁸ Fargen et al, ¹⁸⁹ Fourcade et al, ⁴⁵ Bohmer et al, ¹⁹⁰ Petrovic et al, ¹⁴⁷ Sewell et al, ¹⁴⁹ Kearns et al, ¹⁹¹ Takala et al, ¹⁹² Helmio et al, ¹⁹³ Ali et al, ¹⁹⁴ Haynes et al, ¹ Calland et al, ¹⁵⁰ Nilsson et al, ¹⁹⁵ Haynes et al ¹⁶²
Focus Group	3	Haugen et al, ¹⁸⁶ Braaf et al, ¹²⁵ Spence et al ¹⁷⁸
Interviews	11	Schwendiman, ¹³⁵ Ziman et al, ¹⁶⁸ Dharampal et al, ¹⁹⁶ Braaf et al, ¹²⁵ Aveling et al, ¹⁷⁵ Fourcade et al, ⁴⁵ Healy et al, ¹⁹⁷ Helmio et al, ¹⁹³ Bandari et al, ¹⁹⁸ Conley et al, ¹⁹⁹ Papaspyros et al ¹⁵⁶
Systematic Review	11	de Jager et al, ²⁰⁰ Treadwell et al, ⁴² Thomassen et al, ²⁰¹ Bergs et al, ²⁰² Lyons et al, ²⁰³ Patel et al, ²⁰⁴ Tang et al, ²⁰⁵ Russ et al, ²⁰⁶ Zuckerman et al, ²⁰⁷ Borchard et al, ²⁰⁸ Ko et al ²⁰⁹
Review of Records	22	Belykh et al, ²¹⁰ Lee et al, ²¹¹ Westman et al, ²¹² Ahmad et al, ²¹³ O'Leary et al, ²¹⁴ Jammer et al, ²¹⁵ Lepanluoma et al, ¹⁸⁴ Saturno et al, ¹⁴⁰ Flint et al, ²¹⁶ Hommelstad et al, ²¹⁷ Kubilay et al, ²¹⁸ Aveling et al, ¹⁷⁵ Fourcade et al, ⁴⁵ Yuan et al, ²¹⁹ Kasatpibal et al, ²²⁰ de Vries et al, ¹⁵⁴ Oszvald et al, ²²¹ Rahman et al, ²²² Ali et al, ¹⁹⁴ Truran et al, ²²³ de Vries et al, ¹⁵⁵ Blanco et al ²²⁴
Video Recordings	1	Calland et al ¹⁵⁰

The numerical analysis of the included studies provides the range of outcome measures with the total number of identified studies from the initial scoping review. The summary table can be found below in *Table 3-3: Summary of Outcome Measures (2008-2019)*.

Table 3-3: Summary of Outcome Measures (2008-2019)

Outcome Measure	Total Studies	Study References (2008-2019)
Mortality / Morbidity	19	Ahmad et al, ²¹³ Lacassie et al, ²²⁵ Mayer et al, ¹³⁷ O'Leary et al, ²¹⁴ de Jager et al, ²⁰⁰ Jammer et al, ²¹⁵ Haugen et al, ²²⁶ Urbach et al, ²²⁷ Treadwell et al, ⁴² Thomassen et al, ¹⁶⁰ Bergs et al, ²⁰² Lyons et al, ²⁰³ Lubbeke et al, ¹⁴³ van Klei et al, ¹⁴⁶ Sewell et al, ¹⁴⁹ Weiser et al, ¹⁵³ de Vries et al, ¹⁵⁴ Vats et al, ⁴³ Haynes et al ¹
Complications	32	Belykh et al, ²¹⁰ Lee et al, ²¹¹ Westman et al, ²¹² Ahmad et al, ²¹³ Mayer et al, ¹³⁷ O'Leary et al, ²¹⁴ de Jager et al, ²⁰⁰ Lepanluoma et al, ²²⁸ Haugen et al, ²²⁶ Urbach et al, ²²⁷ Ryan et al, ²¹¹ Thomassen et al, ¹⁶⁰ Bergs et al, ²⁰² Lubbeke et al, ¹⁴³ Fargen et al, ¹⁸⁹ Flint et al, ²¹⁶ Hommelstad et al, ²¹⁷ Kubilay et al, ²¹⁸ Bliss et al, ¹⁴⁵ van Klei et al, ¹⁴⁶ de Vries et al, ¹⁵⁴ Rahman et al, ²²² Sewell et al, ¹⁴⁹ Askarian et al, ¹⁵¹ Lyons, ¹⁵² Weiser et al, ¹⁵³ de Vries et al, ¹⁵⁵ Vats et al, ⁴³ Harrop et al, ¹⁶¹ Haynes et al, ¹ Blanco et al, ²²⁴ Rosenberg et al ¹⁶⁷
Compliance / Adherence	36	Schwendiman, ¹³⁵ Ziman et al, ¹⁶⁸ Sendlhofer et al, ¹⁶⁹ Saturno et al, ¹⁴⁰ Kawano et al, ¹⁸² Cullati et al, ¹⁷⁴ Thomassen et al, ¹⁶⁰ Patel et al, ²⁰⁴ Rydenfält et al, ¹⁷⁰ Poon et al, ¹⁷¹ Sparks et al, ¹⁷² Hannam et al, ¹⁷³ Cullati et al, ¹⁸³ Haugen et al, ²²⁹ Papaconstantinou et al, ¹⁸⁷ O'Connor et al, ¹⁸⁸ Aveling et al, ¹⁷⁵ Pickering et al, ¹⁴⁴ Levy et al, ¹⁷⁶ Sheena et al, ¹⁷⁷ Fourcade et al, ⁴⁵ Kasatpibal et al, ²²⁰ Bandari et al, ¹⁹⁸ Borchard et al, ²⁰⁸ Spence et al, ¹⁷⁸ Vogts et al, ¹⁴⁸ Sewell et al, ¹⁴⁹ Haynes et al, ¹ de Vries et al, ¹⁵⁴ Weiser et al, ¹⁵³ de Vries et al, ¹⁵⁵ Vats et al, ⁴³ Norton et al, ¹⁵⁸ Haynes et al, ¹⁶² Johnston et al, ¹⁶⁴ Rosenberg et al ¹⁶⁷
Team Performance	18	Thomassen et al, ¹⁶⁰ Lyons et al, ¹⁵² Fargen et al, ¹⁸⁹ Russ et al, ²⁰⁶ Pickering et al, ¹⁴⁴ Healy et al, ¹⁹⁷ Bohmer et al, ¹⁹⁰ Sewell et al, ¹⁴⁹ Kearns et al, ¹⁹¹ Takala et al, ¹⁹² Helmio et al, ¹⁹³ Ali et al, ¹⁹⁴ Calland et al, ¹⁵⁰ Lingard et al, ⁴⁷ Papaspyros et al, ¹⁵⁶ Norton et al, ¹⁵⁸ Thomassen et al, ²⁰¹ Lingard et al ¹⁶⁵

Table 3 3: Summary of Outcome Measures (2008-2019) - Continued

Outcome Measure	Total Studies	Study References (2008-2019)
Team Perceptions	31	Ziman et al, ¹⁶⁸ Magill et al, ¹⁸⁰ Dharampal et al, ¹⁹⁶ Haugen et al, ¹⁸⁶ Saturno et al, ¹⁴⁰ Kawano et al, ¹⁸² Cullati et al, ¹⁸³ McLaughlin et al, ¹⁸⁵ Patel et al, ²⁰⁴ Rydenfält et al, ¹⁷⁰ Poon et al, ¹⁷¹ Sparks et al, ¹⁷² Hannam et al, ¹⁷³ Cullati et al, ¹⁸³ Haugen et al, ¹⁸⁶ Papaconstantinou et al, ¹⁸⁷ O'Connor et al, ¹⁸⁸ Aveling et al, ¹⁷⁵ Levy et al, ¹⁷⁶ Sheena et al, ¹⁷⁷ Fourcade et al, ⁴⁵ Helmio et al, ¹⁹³ Bandari et al, ¹⁹⁸ Vogts et al, ¹⁴⁸ Haynes et al, ¹ Conley et al, ¹⁹⁹ Ko et al, ²⁰⁹ Papaspyros et al, ¹⁵⁶ Nilsson et al, ¹⁹⁵ Einav et al, ¹⁵⁷ Haynes et al ¹⁶²
Patient Safety	8	Lepanluoma et al, ²²⁸ Tang et al, ²⁰⁵ Zuckerman et al, ²⁰⁷ Spence et al, ¹⁷⁸ Styer et al, ¹⁷⁹ Papaspyros et al, ¹⁵⁶ Einav et al, ¹⁵⁷ Buzink et al ¹⁵⁹
Feasibility / Effectiveness	5	Braaf et al, ¹²⁵ Fourcade et al, ⁴⁵ Borchard et al, ²⁰⁸ de Vries et al, ¹⁵⁵ Buzink et al ¹⁵⁹
Process Improvements	16	Wong et al, ¹⁸¹ Ryan et al, ¹⁴² Yuan et al, ²¹⁹ Petrovic et al, ¹⁴⁷ Oszvald et al, ²²¹ Styer et al, ¹⁷⁹ Ali et al, ¹⁹⁴ Calland et al, ¹⁵⁰ Truran et al, ²²³ Lyons, ¹⁵² de Vries et al, ¹⁵⁵ Norton et al, ¹⁵⁸ Thomassen et al, ¹⁶⁰ Henrickson et al, ¹⁶³ de Vries et al, ¹⁵⁴ Verdaasdonk et al ¹⁶⁶

The thematic analysis of the included studies provides the number of studies per year for each method and outcome measure category. The total number of identified studies in each year are provided in the summary table below: Table 3 4: Summary of Methods and Outcome Measures by Study Year (2008-2019).

Table 3-4: Summary of Methods and Outcome Measures by Study Year

Year	No. Studies	Methods								Outcome Measure							
		Observation – Quantitative	Observation – Qualitative	Questionnaire / Survey	Focus Group	Interviews	Systematic Review	Review of Records	Video Recordings	Mortality / Morbidity	Complications	Compliance / Adherence	Team Performance	Team Perceptions	Patient Safety	Feasibility / Effectiveness	Process Improvements
2019	2	1	1			1		1			1	1					
2018	3		2			1		1			1	2		1			
2017	3			1				2		1	2			1			
2016	6	2		1		1	1	1		4	3			1			1
2015	4	2			1			2		2	2			1			
2014	13	3		4			6	1		5	4	5	2	5	2		1
2013	17	2	7	4	1	2	1	4		1	5	10	3	9		1	
2012	17	4	2	3		4	2	6		1	4	6	2	5	1	2	3
2011	16	6	2	7	1	1	1	3	1	1	2	5	7	4	2	1	4
2010	12	11		1		1				3	5	4	3	3	3	1	4
2009	5	4		1				1		1	2	2		1			2
2008	3	3									1	1	1				1

3.4.2.1 Key Findings

The initial scoping review was conducted to cover the search strategy between 2008 and 2012. The search strategy was conducted again in 2019 to identify additional studies between 2013 and 2019. The scoping review identified that empirical research investigating surgical checklists was active in 2008 and 2009; however, research in this area peaked between 2010 and 2014. This finding coincides with implementation of the WHO SSC and the associated publication of the global study in 2009.¹

3.4.2.1.1 Numerical Analysis: Methods

The scoping review found that between 2008 and 2012, 53 studies were conducted. From these, the findings indicate that the most frequently adopted methods were 'Observation' [32], 'Questionnaire / Survey' [12], and 'Review of Reports' [10]. These studies indicate that a quantitative observational approach to investigating surgical checklist use was most common [28]. In the remaining studies, a qualitative observational approach was adopted [4]. Observation of surgical checklist use in practice was common during this period, representing an overall focus on quantitative methods within this period. The findings indicate that direct observation is a method commonly applied to the study of WAD, which is supported by Catchpole et al.²³⁰ All of these studies during this period were conducted in developed countries.

From 2013 to present, the studies predominantly utilised 'Observation' [20], 'Questionnaire / Survey' [10], 'Interviews' [5], and 'Review of Records' [12]. Direct observation continues to be the most common method applied to investigate surgical checklist use. However, others have attempted to measure performance via objective methods; Sparks et al developed a tool to score checklist completion and accuracy by taking an aggregate score and demonstrated similar findings to the observational studies.¹⁷²

Qualitative methods mostly employ an ethnography approach involving 'Questionnaire / Survey', 'Interviews',¹⁸⁸ and 'Records Review'.⁸⁷ In addition, investigation methods utilising 'Video Recording' was only applied in 1 study

[1]. Early studies lacked qualitative approaches; investigating team perceptions related to surgical checklist use benefit from a qualitative approach, specifically those including interviews and focus groups.^{231,232} From 2011, systematic reviews [11] were conducted to evaluate the empirical studies designed to investigate surgical checklist use. The majority of these studies were published in 2014 [6].

The scoping review did not identify any studies applying a theoretical framework to investigate surgical checklist use in practice. Overall, the findings illustrate that a range of methods have been applied to the study of surgical checklist use in practice; however, no standardised methodology has been proposed to date.¹⁷¹

3.4.2.1.2 Numerical Analysis: Outcome Measures

The scoping review found that between 2008 and 2012, 53 studies were conducted. From these studies, the findings indicate that studies focused on clinical outcomes [20]: 'Mortality / Morbidity' [6] and 'Complications' [14]. Additionally, studies focused on 'Compliance / Adherence' [18]. These studies indicate that surgical checklists use was investigated in terms of their impact on patient safety improvements. Prior to the implementation of the WHO SSC, earlier studies focused on team performance as a facilitator to surgical checklist use, frequently citing communication issues.^{34,35,38,40,233,234} These studies focused on the transfer of non-technical skills from other high-risk industries and highlighted the benefit of surgical checklists to improve teamwork and performance.^{20,55,235,236} The scoping review identified non-technical skills related outcome measures: 'Team Performance' [13], 'Team Perceptions' [13], and 'Process Improvements' [14] to theatre team performance and perceptions. Additionally, 'Compliance / Adherence' and 'Team Perceptions' were frequently combined as outcome measures.²³⁷ There was less focus on 'Patient Safety' and 'Feasibility / Effectiveness' as outcome measures.

From 2013 to 2019, the studies predominantly investigated clinical outcomes as 'Mortality / Morbidity' [13] and 'Complications' [18]. This finding illustrates an increased focus on these outcome measures during this period. There was increased focus on 'Compliance / Adherence' [18] and 'Team Perceptions' [18]. There was a notable reduction in focus on other outcome measure, specifically 'Process Improvement' [2].

3.4.2.1.3 Thematic Analysis

The thematic analysis identified high-level trends in the approaches applied to investigate surgical checklists. From 2015 to 2019, there was a large reduction in the number of studies published per year [2 to 6] compared to the period 2010 to 2014 [12 to 17]. The largest percentage of the studies identified in the scoping review were published from 2010 to 2014 (75%). The studies published after 2014 have primarily used 'Observation' [8], 'Interviews' [3], and 'Review of Records' [7]. The associated outcome measures were focused on clinical outcomes ('Mortality / Morbidity' and 'Complications') [16], 'Team Perceptions' [4], and 'Compliance / Adherence' [3]. Up to 2012, there was a large number of studies evaluating surgical checklist use related to 'Process Improvement' [14]. From 2013 to 2019, there have been limited further studies [2].

The thematic analysis identified that in the studies utilising observation methods, the types of surgical specialties observed varied greatly. Overall, twenty different types of surgery were reported in observation studies. The least popular surgical specialties included in observation studies were cancer surgery, spine surgery, hernia surgery, and gastro-intestinal surgery. Cardiovascular surgery, orthopaedic surgery, and neurosurgery were the most frequently observed. In earlier research, observations in neurosurgery were limited due to lengthy procedures;²⁰⁴ however, this was highlighted as a deficiency in literature, and awareness was raised for the reported benefits of surgical checklists in other surgical specialties to be applied to neurosurgery.²⁰⁷

Specific information detailing why each type of surgery was selected for inclusion in the study was limited. Overall, the implementation of surgical checklists were linked to prevention of adverse events, reduction of errors and surgical complications, and improved communication between theatre team members. However, some studies linked the need for surgical checklist implementation to specific issues within the surgical specialty under observation; examples are as follows:

- General surgery was reported to have a need for surgical checklists to improve compliance to venous thromboembolism (VTE) guidelines.
- Laparoscopic surgery was reported to have a need for surgical checklists due to a high incidence of issues with technical equipment and a high rate of adverse events.
- Cerebrovascular surgery was reported to have a need for surgical checklists due to a high ventriculostomy infection rate which resulted in significant morbidity rates.
- Shunt surgery was reported to have a need for surgical checklists due to high shunt infection rates.
- Neurosurgery was reported to have a need for surgical checklists to maintain and improve patient safety in the operating theatre. In addition, the unique demands of neurointerventional procedures were highlighted as being relevant for implementation of surgical checklists.

Overall, a common theme relates to patient safety improvement needs across all surgical specialties. Therefore, with such a wide range of surgical specialties, it is not possible to identify any trends which would determine selection of one type of surgical specialty over another in observation studies. In *Chapter 5: Empirical study I*, Table 5.1 provides the types of surgical specialties included in the observation study: elective orthopaedic surgery, trauma orthopaedic surgery, plastic surgery, and vascular surgery. These surgical specialties were not selected for any previously identified improvement needs; they were selected as the most frequently performed surgical specialties at the participating hospitals. Therefore, a high frequency

of operations was the primary decision for inclusion of these surgical specialties.

The thematic analysis found inconsistencies and variations in reporting style, which made it complex to confirm any causal relationships between the implementation of surgical checklists and positive impacts on outcome measures. However, the implementation of surgical checklists was reported to have multiple positive impacts on a variety of outcome measures. Studies reported one or more positive outcomes, as follows:

- A high number of studies reported that the implementation of surgical checklists had a positive impact on clinical outcome measures [22].
- Some studies reported that the implementation of surgical checklists had a positive impact on process improvements [6].
- Some studies reported that the implementation of surgical checklists had a positive impact on non-technical skills such as communication and situational awareness [6].
- A high number of studies reported that the implementation of surgical checklists had a positive impact on staff perceptions and attitudes i.e. increased satisfaction and improved safety culture [11].
- One study reported that the implementation of surgical checklists had a positive impact on outcomes; however, it suggested that this finding may be related to poor study design and confounding factors.¹⁹⁶

Other studies reported positive outcomes related to the implementation of surgical checklists when combined with briefings and debriefings [9]. Additionally, combining the implementation of surgical checklists with team training and education were reported as necessary to achieve positive impacts on outcome measures [4]. Two studies reported minimal improvement, and another reported that extrapolation of benefits related to surgical checklist implementation should be applied with caution.¹⁷³

A high number of studies did not specify whether the implementation of surgical checklists was related to positive outcomes [13]; they commented that

there was a possibility of improvements and that further work was required. A small number of studies reported no positive impacts on outcomes [2]; one specifically commented that this may be a result of poor surgical checklist implementation and dissemination strategy.¹⁷⁶

Ascertaining conclusive evidence of a causal relationship between the implementation of surgical checklists and positive impacts on outcomes is limited by reporting issues and unknown factors excluded in the existing literature. The analysis approach and reporting are not standardised across observation studies. The terminology used in reporting differs; in addition, the reporting of multiple methods and multiple outcomes within one study limits the ability to determine positive impacts related solely to the implementation of surgical checklists.

The thematic analysis found that the reporting of interactions between observed surgical specialty, methodological approach, and outcome measures is extremely variable. A study by study analysis may be necessary as several limitations render it impossible to compare between studies. Comparison between studies to identify themes is confounded by the varying ways in which the effectiveness of surgical checklist implementation is measured. Examples of variances are outlined below:

- Within the study method of observation, numerous variances were identified such as the training of observers, the data collection tools used, and how the observations were conducted.
- A vast range of surgical specialties were observed; in some studies a single type of surgery was observed and in other studies multiple surgical specialties were observed.
- Observations were conducted at a single hospital site or across multiple hospital sites.
- The periods of observation varied from a number of weeks to more than one year.

In addition to the above variances, when comparing between observation studies that have the same outcome measure, further variations were

identified. For example, observation studies measured compliance, theatre team perceptions, clinical outcomes, and a combination of these outcomes. Even when the same outcome measure was reported, variations in the detail were identified; for example, when compliance was measured, some studies measured a single data point for performance, and others measured multiple data points for compliance.

Explaining why and how surgical checklists are implemented is considered important to understand their effectiveness;²⁰⁸ however, a lack of standardisation in the design and execution of studies makes this difficult to explore. Therefore, reporting of studies is extremely variable in the current literature and limits the conclusion of any informative themes.

The scoping review update identified more opinion pieces than in previous years; however, these were excluded in this scoping review as they did not meet the inclusion criteria. This illustrates the necessity to continue to evaluate recent work and update the scoping review throughout the research period; this iterative approach supports understanding of the current state of knowledge. However, conducting multiple scoping reviews made reporting of the results more complex. Analysing the work of others to interpret key concepts was difficult as limited understanding of the background to WAD had been provided in the identified studies. In addition, themes were often embedded with others; therefore, trends cannot be clearly identified.

3.4.2.2 Limitations

The scoping review examined peer reviewed studies; these were reviewed to identify methodological approaches and associated outcome measures. The overall key concepts were identified at a high-level; however, categorisation of the study data was complex due to inconsistencies in reporting.

The chronology was aimed to establish any trends found between 2008 and 2019. However, with published research, there is a delay between the research completion and publication date. An attempt was made to identify

study periods, although this information was inconsistently reported, which restricted the chronology organisation to the published date. This had an impact on the true representation of any identified trends. The search terms were designed to ensure that a comprehensive search strategy was employed. While every attempt was made to achieve full coverage, some studies may have been missed. Further limitations which are generic to scoping reviews are highlighted in *Chapter 7: Discussion and Conclusions*.

3.5 Motivation for this Research

Exposure to the research area and the findings of the scoping review identified a significant research gap in existing literature. The findings of others in this area indicate that WAI is misaligned with WAD with little evidence related to how surgical checklists are used in practice. Therefore, no conclusive evidence was found to demonstrate how surgical checklists are used in a descriptive account of WAD.

The scoping review findings support the investigation of officially mandated checklists; however, no evidence was found related to the investigation of unofficial surgical checklist use. Therefore, an in-depth study of how checklists are used by theatre teams in surgical settings was justified. A mixed methods approach and the application of a theoretical stance from DCog was considered to provide a novel insight into the understanding of surgical checklist use in current practice, thereby advancing knowledge in this research area.

Chapter 4 Research Process

4.1 Overview of the Chapter

In this chapter, an overview of the research process undertaken in this thesis will be presented. The research background which led to the motivation for this research area will be briefly explained. An introduction will be provided for the research paradigms and theoretical frameworks considered in this research. In addition, the research questions will be presented with an outline of the methodology employed to address these questions. Finally, the ethical considerations will be explained.

4.2 Declarations

None to declare for this chapter.

4.3 Introduction to the Research Process

The research process explains the decision stages to conduct this research.

These stages include:

- selecting an appropriate research paradigm
- defining research questions
- identifying an appropriate methodology
- selecting the research design and methods
- selecting an applicable theoretical framework.

4.4 Research Background

Firstly, I will summarise the background to this research to highlight important factors which contributed to this work. The opportunity for this research was based on a larger research project called '*The S3 Project: Safer Delivery of Surgical Services*.'²³⁸ The S3 Project was an observational and quality improvement study which took place at multiple NHS Trust hospitals across the UK as a collaboration between the *University of Oxford* and *Warwick Orthopaedics, Warwick Medical School*, funded by the *National Institute for Health Research* under its Programme Grants for Applied Research: reference no. RP-PG-0108-10020.

As part of the S3 Project, I was employed as a research associate due to my background in psychology, aeronautical engineering, and HF. My role in the S3 Project was as an HF observer, and I was trained to observe theatre teams at work in the operating theatre. As part of this training, I learnt about the operating theatre environment, the surgical process flow, and non-technical skills related to theatre team members' performance. I was one of four full-time researchers employed on the S3 Project. Specific information regarding detailed training can be found in *Chapter 5: Empirical Study I*. Permission to observe theatre teams in the operating theatre was granted at each participating hospital via an observer research passport.

As a full-time research associate on the S3 Project, I enrolled in a PhD in Medical Sciences, registered at *Warwick Medical School*, the *University of Warwick* on a part-time basis. During the S3 Project, each researcher was given the opportunity to lead an area of the research. Throughout my career, I had worked on checklists in aviation, and I had a specific interest in the debate surrounding surgical checklist use in healthcare. The WHO SSC was identified as a key area of interest for the S3 Project and was investigated as part of the improvement interventions. The S3 Project team agreed that I could lead this area of research and that the data could be utilised in partial fulfilment of my PhD. Therefore, the WHO SSC data collected during the pre-intervention phase of the S3 Project was utilised for *Empirical Study I*; more details can be found in *Chapter 5: Empirical Study I*.

4.5 Research Paradigms

It is important to frame research in a paradigm to guide the investigation. Kuhn described a research paradigm as shared common beliefs about understanding and addressing problems.²³⁹ Similarly, Guba described paradigms as a belief that can be used to guide action to a disciplined inquiry.²⁴⁰

In research, utilising a checklist can be viewed in two ways. The checklist can be viewed in terms of the associated outcomes with its use, i.e. does using a checklist contribute to improvements? Alternatively, it can be viewed as a tool, acting as an artefact in the wider system, i.e. how is the checklist used in practice? This research aims to study how surgical checklists are used in practice; therefore, appropriate research paradigms were considered to guide the research.

Originally, Guba proposed four research paradigm categories: positivism, post-positivism, critical theory, and constructivism.²⁴⁰ Over time, others expanded the categories to include additional paradigms; all can be defined by fundamental characteristics according to their ontology, epistemology, and

methodology. A summary of paradigms is provided in *Table 4-1: Paradigm Characteristics* below.

Table 4-1: Paradigm Characteristics

Paradigm	Ontology What is reality?	Epistemology How can reality be known?	Theoretical Perspective Which theory based approach to apply?	Methodology What approach is most suited to acquire knowledge?	Method What tools and techniques are appropriate?
Positivism	There is a single reality or truth	Reality can be measured hence the focus is on reliable and valid tools	Positivism Post positivism	Experimental research Survey research	Quantitative: Sampling Measurement and scaling Statistical analysis Questionnaire Focus group Interview
Constructivist / Interpretive	There is no single reality or truth. Reality is created by individuals in groups (less realist).	Reality needs to be interpreted. It is used to discover the underlying meaning of events and activities.	Interpretivism (reality needs to be interpreted) • Phenomenology • Symbolic interactionism • Hermeneutics Critical inquiry Feminism	Ethnology Grounded Theory Phenomenological research Heuristic inquiry Action Research Discourse Analysis Feminist Standpoint research etc.	Qualitative: Qualitative interview Observation Participant Non-participant Case study Life history Narrative Theme identification etc.
Pragmatism	Reality is constantly renegotiated, debated, and interpreted in light of its usefulness in new, unpredictable situations.	The best method is one that solves problems. Change is the underlying aim.	Deweyan pragmatism <i>Research through design</i>	Mixed methods Design-based research Action research	Combination of any of the above, such as data mining, expert review, usability testing, and physical prototype.
Subjectivism	Reality is what we perceive to be real.	All knowledge is purely a matter of perspective.	Post modernism Structuralism Post-structuralism	Discourse theory Archaeology Genealogy Deconstruction etc.	Autoethnography Semiotics Literary analysis Intertextuality etc.
Critical	Realities are socially constructed entities that are under constant internal influence.	Reality and knowledge are both socially constructed and influenced by power relations from within society.	Marxism Queer theory Feminism	Critical discourse analysis Critical ethnography Action research Ideology Critique	Ideological review Civil actions, open-ended interviews, focus groups, open-ended questionnaires, open-ended observation, and journals.

Adapted from Hay 2002 pg64. / Crotty 1998 / Salmapatel²⁴¹⁻²⁴³

In order to identify the appropriate paradigm, an interpretation of the research decision stages was followed; see *Figure 4-1: Interpretation of Research Decision Stages* below.

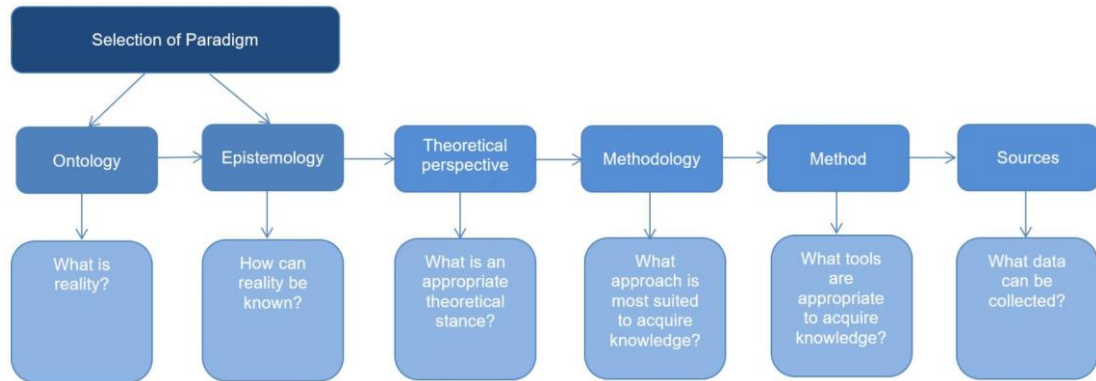


Figure 4-1: Interpretation of Research Decision Stages

Fully aligning this research with the appropriate paradigm was partly determined by the S3 Project, which is further explained below in *Section 4.7: Research Methodology*. This research neither evaluates surgical checklist design characteristics, nor is it concerned with questioning if the implementation of surgical checklists is appropriate as a safety tool in surgical practices. This research is not aimed to test a theory; it is aimed to investigate how surgical checklists are used in practice. Therefore, this research was determined to align more closely with the interpretive paradigm.

The preliminary literature review and the scoping review (*Chapter 3: A Scoping Review*) identified that various approaches have been applied to investigate surgical checklist use and the associated outcomes. However, investigations are limited related to a descriptive account of how surgical checklists are used in practice. This identified gaps and limitations in the existing literature, and further questions were defined for investigation in this research.

4.6 Research Questions

This research investigates the following overarching research question:

How do theatre teams currently use surgical checklists in practice?

In order to address this question, three research questions were defined and are investigated in the current research.

Firstly, research question one (RQ1 below) was defined to establish what information was available in the existing literature. This question was addressed previously in *Chapter 3: A Scoping Review*.

RQ1: What methodologies are applied to investigate how surgical checklists are used in practice, and what are the associated outcome measures?

Secondly, research question two (RQ2 below) was defined to investigate how a formal checklist which is enforced as a national requirement is used in practice. Establishing WAD related to compliance is aimed to partly address the overarching research question. To fully address this question, associated objectives were defined (see below). This question and the associated objectives will be addressed in *Chapter 5: Empirical Study I*.

RQ2: What is the current level of compliance to the WHO SSC in practice in UK hospital operating theatres?

Specific primary and secondary objectives to address RQ2 are provided below.

Primary objectives:

I-O-1: to assess theatre team members' attempts at performing the WHO SSC time-out and sign-out sections.

I-O-2: to assess the quality of theatre team members' performance for the WHO SSC time-out and sign-out sections.

Secondary objectives:

- I-O-3: to assess if there is a difference in theatre team members' performance for the WHO SSC time-out and sign-out sections between NHS Trusts.
- I-O-4: to assess if there is a difference in theatre team members' performance for the WHO SSC time-out and sign-out sections between surgical specialties.
- I-O-5: to assess if there is an association between the WHO SSC time-out quality of performance and the sequential attempt of the sign-out.
- I-O-6: to assess performance time of conducting the WHO SSC time-out and sign-out sections.
- I-O-7: to assess if there is an impact of leader on the quality of performance for the WHO SSC time-out section.

Thirdly, research question three (RQ3 below) was defined to investigate how an informal checklist provided at the local level is used in practice. To fully address this question, associated objectives were defined (see below). This question and the associated objectives will be addressed in *Chapter 6: Empirical Study II*.

RQ3: How do theatre teams use a surgical checklist to prepare the operating theatre for hip arthroscopy surgery?

Specific objectives to address RQ3 are below:

- II-O-1: to describe the key interactions within the pathway of preparing the operating theatre for surgery using DCog as a guiding theoretical framework.
- II-O-2: to identify key information sources in the form of artefacts used by theatre team members to prepare the operating theatre for hip arthroscopy surgery.
- II-O-3: to highlight knowledge distribution issues during preparation of the operating theatre for hip arthroscopy surgery.
- II-O-4: to suggest areas for the redistribution of knowledge to inform the design of future surgical checklists as cognitive artefacts.

4.7 Research Methodology

From selecting a research paradigm, an appropriate research methodology was identified. It was determined that in order to effectively study how surgical checklists are used in practice, a practice-based approach was most suitable. Practice theories are concerned with activity and performance at work.²⁴⁴ The practice of work covers many aspects. When referring to practice, this research is neither concerned with the surgical procedure from a technical perspective nor does it intend to redesign technical equipment used in the operating theatre. This research considers human performance aspects of work in the operating theatre. Therefore, practice relates to the interactions within the environment under study, i.e. the operating theatre comprising of clinical practitioners' performance, the artefacts in use, and other relevant interactions.

Various practice-based approaches could have been adopted in this research. For example, the methods applied in HF, Safety I, Safety II and Resilience Engineering have all utilised ethnography methods to study WAD, enabling the study of humans at work in the naturalistic setting.^{230,245-248} Therefore, viewing the checklist as a tool and investigating how it is used is best studied in a naturalistic setting. This approach is applicable for this research as observation of theatre teams at work within the operating theatre is necessary to gain the most realistic insight. The operating theatre is a complex and dynamic environment; therefore, methods appropriate for the environmental context were necessary. The culmination of these factors aided the selection of an appropriate methodology robust in methods whilst enabling an exploratory and holistic approach.

4.7.1 Research Design and Methods

The S3 Project facilitated initial exposure to the research area. In addition, knowledge from experience and an understanding of the research area from preliminary literature aided in identification of potential issues. The research area was further defined via the scoping review findings (*Chapter 3: A Scoping*

Review). A high-level overview of the research design and methods is provided in this section with more detail provided in the relevant chapters (*Chapter 5: Empirical Study I* and *Chapter 6: Empirical Study II*).

After selection of the appropriate research paradigm, the next stage was to identify an appropriate research design based on the overarching research question. Each research question required an appropriate method; *Table 4-2: Summary of Selected Research Methods* below shows the methods selected to address each research question, with additional detail below.

Table 4-2: Summary of Selected Research Methods

Research Question	Chapters	Methodology	Methods					
			Scoping Review	Observations				
				Direct observation	Shadowing	Freehand notes	Unstructured notes	Video recording
1	1, 2, 3	Research Clarification	✓					
2	5	Empirical Study: Quantitative and Descriptive		✓				
3	6	Empirical Study: Qualitative and Exploratory		✓	✓	✓	✓	✓

To address:

RQ1: What methodologies are applied to investigate how surgical checklists are used in practice, and what are the associated outcome measures?

A scoping review was conducted, allowing for a comprehensive review of existing literature to map the methodologies applied to investigate surgical checklist use and the associated outcome measures. Further details can be found in *Chapter 3: A Scoping Review*.

To address:

RQ2: What is the current level of compliance to the WHO SSC in practice in UK hospital operating theatres?

RQ3: How do theatre teams use a surgical checklist to prepare the operating theatre for hip arthroscopy surgery?

Two empirical studies were conducted: RQ2 is addressed in *Empirical Study I*, and RQ3 is addressed in *Empirical Study II*. Both studies utilise direct observations of theatre teams at work. A mixed methods approach was selected, and each study was designed to observe how a specific type of surgical checklist is used in practice. Specifically, *Empirical Study I* will establish the extent to which a formal checklist is used and will capture current practice. *Empirical Study II* will extend this knowledge by investigating how a locally developed checklist is used in practice. The combined findings are aimed to inform future surgical checklist use.

Figure 4-2: Empirical Studies: Overview of Research Methodology and Methods below illustrates the research methodology and methods selected for *Empirical Study I* and *Empirical Study II*.

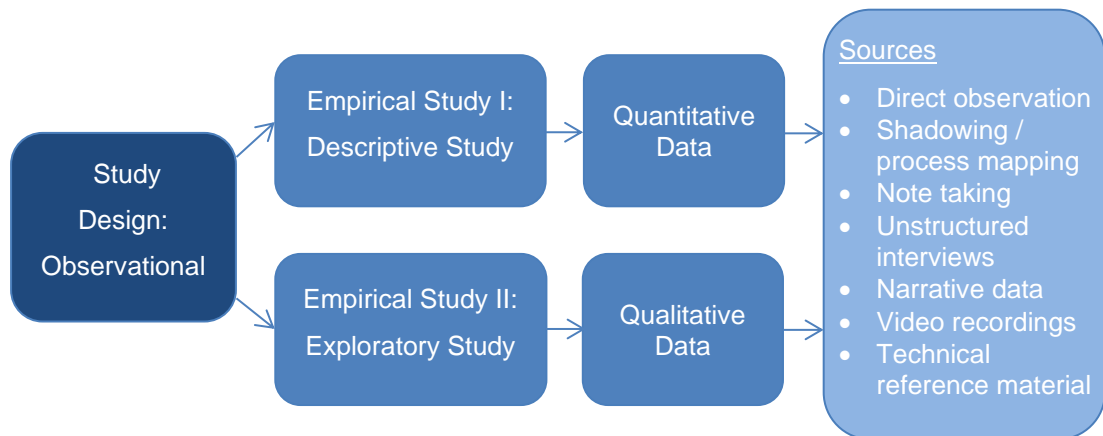


Figure 4-2: Empirical Studies: Overview of Research Methodology and Methods

4.7.1.1 Empirical Study I

Empirical Study I was conducted as part of the S3 Project. This had specific implications for the study design as it was embedded within a larger complex study design which was a suite of controlled interrupted time series experiments. The S3 Project delivered three improvement interventions in different combinations; each individual study had a pre-intervention observation period, an intervention period, and a post-intervention observation period. The study design employed direct observation with pre-planned pooled analysis to identify the effects of individual interventions, intervention combinations, and confounding variables.

Empirical Study I employed a descriptive approach to observe WAD via the collection of quantitative data during the pre-intervention phase of the S3 Project. Direct observation provided an insight into surgical checklist adherence in UK hospitals. This approach aimed to establish how a mandatory surgical checklist was used in practice, with two measures of performance: attempts to perform the checklist and the quality of performance. Observation data was statistically analysed.

4.7.1.2 Empirical Study II

Empirical Study II was designed to be conducted in parallel to the S3 Project. Therefore, some restrictions were imposed on the design due to ethics approval. However, this study was designed to advance on the findings of Empirical Study I with an exploratory approach.

To classify the selected study design, the *Centre for Evidence-Based Medicine* was referenced; see *Figure 4-3: The Centre for Evidence-Based Medicine: Research Study Design Tree*²⁴⁹ below.

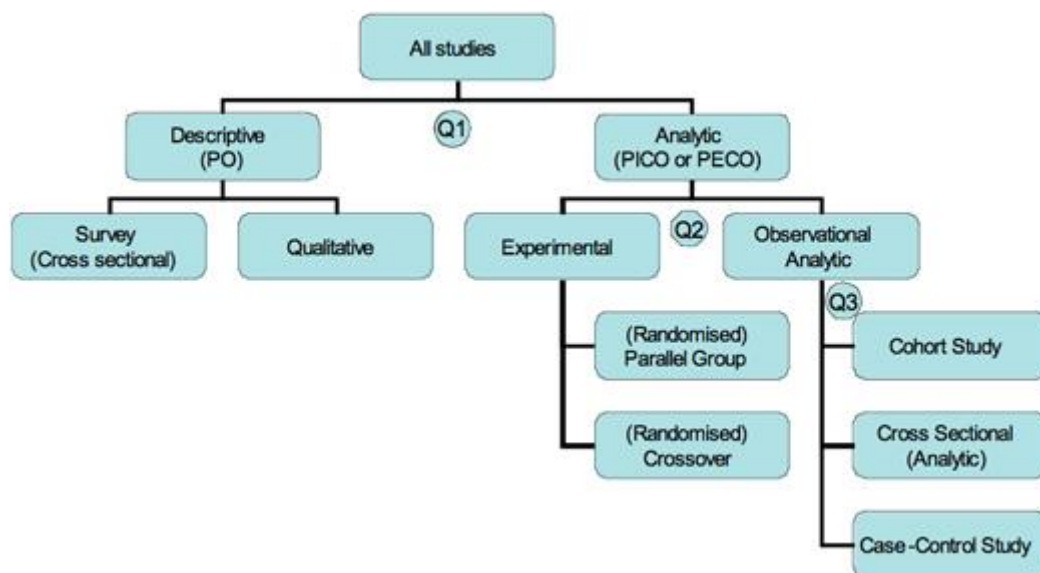


Figure 4-3: The Centre for Evidence-Based Medicine: Research Study Design Tree

The Research Study Design Tree is followed by answering three questions related to the research:²⁴⁹

Q1. What was the aim of the study?

- a) to describe a population (PO questions) = descriptive; or
- b) to quantify the relationship between factors (PICO questions) = analytic.

Q2. If analytic, was the intervention randomly allocated?

Q3. When were the outcomes determined?

Direct observation methods were applied to remain in line with the S3 Project ethics approval and to continue the study of theatre teams in their work setting. Utilising the Research Study Design Tree confirmed that *Empirical Study II* was not intended to apply experimental or analytical observational studies; therefore, interventions (I) and exposures (E) were eliminated.

A qualitative method was selected to apply a more exploratory approach to the study of theatre teams at work by utilising an established theoretical framework. This provided a framework to guide the methodological and analytical approach. Studies which apply an ethnography approach typically generate a vast amount of data; therefore, additional guidance was applied from the Equator Network: standards for reporting qualitative research.²⁵⁰

4.7.2 Theoretical Frameworks

In *Empirical Study II*, a theoretical framework was selected to guide the research approach. Benefits of selecting an appropriate theoretical framework provide a connection to existing research and knowledge, thus guiding the methodological and analytical approach of the study. This provides an established theoretical stance, supporting further understanding and advancement of knowledge in this research area.

Applying a theoretical framework is a common approach to the study of humans at work, and various theoretical frameworks could have been applied to this study. However, the main applicable theories include: DCog, Activity Theory (AT), and Situated Action (SA). Each theoretical framework can be viewed with a specific application to this research area, although either one may benefit from the advancement of knowledge as they are all concerned with human activity at work. As discussed in *Chapter 2: Checklists*, DCog was selected as the theoretical stance as it is applicable to this research interest of checklist use as a cognitive artefact in the joint cognitive system. A brief introduction to AT and SA is given below, with further insight into the application of DCog.

4.7.2.1 Activity Theory: A Brief Overview

Activity Theory (AT) is rooted in soviet psychology. Originating in the 1920s and pioneered by Vygotsky,²⁵¹ Leont'ev and Luria later became principal founders of AT by developing aspects of the original theory. They proposed AT as an approach to the study of human behaviour, with a focus on learning and activity within cultural-historic tradition of soviet psychology, suggesting that humans interact with objects rather than react with their environment.^{252,253} Although AT was primarily developed in Soviet Russia, it was later introduced in the western world by Engeström in the 1980s. In Engeström's seminal work titled: *Learning by expanding*,²⁵⁴ AT was reformulated from Leont'ev's and Luria's views of two entities: the individual and the object. Originally AT proposed that an activity is composed of a subject which is a person or a group that holds an objective in a direction to motivate activity.²⁵⁵ In contrast, Engeström viewed three interacting entities: the individual, the object, and the community.²⁵⁶ As a theoretical framework, AT proposes that individuals are socio-cultural actors in a systems approach. Kutti comments that AT can be used in both proposed senses,²⁵⁷ and Bedny adds that AT is a goal directed activity which requires the integration of cognition, behaviour, and motivation.²⁵⁸

As an analytical framework, AT has been applied to domains concerned with human activity at work. Engeström applied Activity theory in Artificial Intelligence (AI)²⁵⁹ and later to education.²⁶⁰ AT has been extensively applied by others to the field of Human-Computer Interaction (HCI)²⁶¹⁻²⁶³ Additionally, Kutti and Collins et al applied AT in Information Systems,^{257,264} as did Lim and Hang.²⁶⁵ Recently, AT has been applied to healthcare settings.^{266,267} Mishra et al explain that AT contributes to a holistic approach to healthcare studies by focusing on how humans use artefacts to interact with their environment.²⁶⁶ A specific strength of AT as an analytical theory is its ability to enable the in-depth study of context by providing reasons for an activity and explaining actions in the context of goals.

4.7.2.2 Situated Action: A Brief Overview

Situated Action (SA) was developed by Suchman who proposed that an activity comprises of individuals as actors representing the interactions between them and their actions in environments.²⁶⁸ A supporting view by Lave explained that SA should focus on everyday activity of humans acting in a setting rather than the cognitive properties of artefacts or social relations.²⁶⁹

In contrast, Vera and Simon proposed a symbolic representation of cognition and that both approaches to SA could be incorporated.²⁷⁰ This view generated an extensive debate. Norman summarises that the traditional symbolic approach to SA dilutes the external and social factors and the relevance of historical influences.²⁷¹ Nardi explained that the focus of SA is on situated activity or practice rather than knowledge or values.²⁵⁵ Lave adds that SA analysts do not deny that knowledge or values are important.²⁶⁹

SA has a strong application in HCI research. Suchman's work adopted an anthropological approach with a focus on sensemaking of activity, demonstrating how action and planning are situated in activities.²⁶⁸ SA has also contributed to the work by Clancey et al on robotics for autonomous agents.²⁷²

4.7.2.3 Distributed Cognition

Distributed Cognition (DCog) was introduced in *Chapter 2: Checklists*. DCog methodology has similarities with ethnography, which is considered a more holistic approach to studying teams at work. DCog enables a content rich view of a complex environment by applying multiple methods. Halverson refers to the various methods used in applying DCog in context, ranging from video analysis and audio recordings of teams in their work settings to simulations in order to ensure familiarity with working practices through in-depth field work.²⁷³ Further support to this approach is given by Rogers who emphasises the importance of understanding how artefacts are integrated into the complexities of dynamic work settings whereby a multi-dimensional approach is more appropriate.²⁷⁴ The operating theatre is a particularly complex environment

with regard to interactions between individuals and the artefacts they use. Rogers supports the application of DCog as it provides a methodological and analytical framework to highlight interdependencies between individuals within a team and the artefacts they use to collaborate with each other.²⁷⁴

DCog has been extensively applied to HCI research, aiming for improvements in teamwork and task performance by designing new technological systems through the redistribution of tasks to computers. Rogers describes this process as analysing work settings to identify existing problems related to technology and working practices, thereby recommending what can remain and what needs to be redistributed.⁸¹ The advantages of this approach ensures that new ways of working are integrated with existing methods, tools, and technologies.

DCog is branching into healthcare settings as a methodological and analytical approach to study WAD in healthcare environments. The use of DCog in the operating theatre is exemplified by the work of Hazelhurst et al who advocate for the *activity system* as the unit of analysis, proposing DCog as an appropriate theory to apply in healthcare for the study of socio-technical work.²⁷⁵

4.7.2.4 A Brief Comparison Between Theoretical Frameworks

When studying the environmental context of a work setting, it is necessary to understand interactions between individuals at work, the artefacts they interact with, and social groups. Nardi proposes that any of the three social learning theories have value and can be applied to this type of work.²⁵⁵ Considerations of the similarities and differences between the three frameworks highlight specific strengths and limitations of each framework in relation to the others. *Table 4-3: Social Learning Theory Comparison*²⁷⁶ below presents a comparison chart for the three social theories,²⁵⁵ which highlights the main differences in the unit of analysis between the theories. For example, in AT the unit of analysis is an activity; in SA the analysis is focused on actors and human activity. In DCog, cognition and knowledge are not restricted to an

individual; cognition and knowledge are distributed in the environment and spread between individuals, across objects, artefacts, and tools. This comparison contributed to selecting the most appropriate theoretical framework for *Empirical Study II*.

Table 4-3: Social Learning Theory Comparison

	Activity Theory	Situated Action	Distributed Cognition
Unit of Analysis	<ul style="list-style-type: none"> An activity is composed of subject, object and operations Subject: a person/group engaged in an activity Object: is held by the subject & motivates activity, giving it a specific direction Operation: the way an action is carried out; can become routinised and unconscious with practice 	<ul style="list-style-type: none"> The activity of person as acting in settings (not the individual or environment but the relation between them) 	<ul style="list-style-type: none"> A cognitive system composed of individuals and artefacts The cognitive system equals an activity
Context	<ul style="list-style-type: none"> Operations depend on the conditions under which the action is being carried out The activity itself is the context Context is internally and externally unified Context: constituted through the enactment of an activity involving people and artefacts 	<ul style="list-style-type: none"> Setting: a relation between acting persons and the arenas in relation with which they act Arena: a stable institutional framework 	<ul style="list-style-type: none"> The functional system: the system composed of individuals and artefacts

Table 4 3: Social Learning Theory Comparison - Continued

	Activity Theory	Situated Action	Distributed Cognition
Treatment of Actions	<ul style="list-style-type: none"> • Objects can be transformed in the course of the activity (not moment-to-moment but over time, thus the changed object can change the nature of the activity) • Operation can become an action when conditions impede an action's execution through previously formed operations 	<ul style="list-style-type: none"> • Emphasis on responsiveness to environment and improvisatory nature of human activity • Activity grows directly out of the immediacy of the situation • Behaviourist undertones 	<ul style="list-style-type: none"> • Structures (in & out of the head) transform • Cooperating people & artefacts are focus not just individual cognition in the head
Equivalence of People and Things (Artefacts)	<ul style="list-style-type: none"> • Artefacts ≠ people • People are mediated by artefacts • Artefacts possess culture and history, which stretch across activities through space and time 	<ul style="list-style-type: none"> • Artefacts ≠ people 	<ul style="list-style-type: none"> • Artefact = people • Shared goals & plans • Characteristics of the artefact determine interaction and quality of collaboration
Emphasis/ Perspectives	<ul style="list-style-type: none"> • Emphasis on motivation & purposefulness to a goal • Concerned with historical development of activity & mediating role of artefacts 	<ul style="list-style-type: none"> • Individual is not motivated to do the activity, only routine practice 	<ul style="list-style-type: none"> • System goal which does not involve individual consciousness • Takes advantage of artefacts designed by others, sharing ideas across space & time

4.7.2.5 Theoretical Stance: Distributed Cognition as a Guiding Theoretical Framework

DCog was selected as the overarching guiding theoretical framework applied to *Empirical Study II (Chapter 6: Empirical Study II)*. This study considers the operating theatre as a joint cognitive system to understand WAD when using

a cognitive artefact in practice. In this study, the methodological and analytical approach draws on the work of others whereby DCog has been applied to understand the distribution of knowledge between people, artefacts, and tools within a system.^{52,275,277} Therefore, DCog is applied as a guiding framework to understand how the operating theatre is prepared for surgery.

Blandford and Furniss commented that the application of DCog as a methodology has not been well documented and proposed a semi-structured framework referred to as Distributed Cognition for Teamwork (DiCoT).^{277,278} This framework is based on DCog as an approach to reasoning about systems through understanding how information is transformed between numerous people and artefacts to achieve a common goal.²⁷⁷

In this framework, they proposed DiCoT models which support a focused research scope by identifying key aspects in the study of work in the operating theatre. DiCoT is specifically useful to structure the research approach and identify specific focus areas in complex environments.

4.8 Ethics Considerations and Approval

S3 Project ethics approval covered all research undertaken as part of this PhD. This was approved by the S3 Project chief investigator as the content was in line with the S3 Project aims and objectives.

S3 Project ethics were approved by *Oxford A Ethics Committee (REC:09/H0604/39)*. A copy of the S3 Project ethics approval can be found in *Appendix E – S3 Project Ethics Approval*.

4.8.1 Consent to Participate

4.8.1.1 Theatre Team Members (Anaesthetists, Surgeons, Nurses)

The S3 Project enabled the recruitment of participants and covered consent to participate in this research. At the start of the S3 Project, various levels of staff were briefed, i.e. participating hospital management, operating theatre

managers, and theatre teams. Consent to participate was obtained on an individual basis.

All theatre staff recruited to participate in the study were fully briefed by the researchers and consented to participate under ethical approval from the *Oxford A Ethics Committee* (REC:09/H0604/39). Details of the study aims were presented to each potential participant. Consent was obtained outside of the operating theatre prior to the start of the operation, when practicable. If a new member of the operating team unexpectedly joined the operating theatre, a briefing was provided real-time and consent was obtained on the spot. Consent to participate was given by one hundred percent of the briefed participants.

4.8.1.2 Patients

Patient consent was not required by the *Oxford A Ethics Committee*. The research team had no direct interaction with the patients during observations. Patient information was available to the research team via the patient operating list although this information was not required in this research. In addition, most patients were under anaesthetic when entering the operating theatre. All observers wore surgical clothes and masks as a requirement for operating theatre attire and in order to blend in with other theatre team members in the operating theatre.

4.8.2 Data Storage and Handling

All data was de-identified to ensure patient anonymity. Data was stored on *Oxford University* and *Warwick Medical School* password protected computers and was only accessible by the S3 Project research team.

Chapter 5 Empirical Study I: Direct Observation Study of the WHO Surgical Safety Checklist in use in UK Operating Theatres

5.1 Overview of the Chapter

In this chapter, Empirical Study I will be presented with the study aims and objectives. The methodological and analytical approach will be described, and the findings will be presented. The chapter will be concluded with a discussion, and limitations and suggested future work can be found in Chapter 7: Discussion and Conclusions.

5.2 Declarations

Full declarations are detailed in the Declarations section of this thesis.

Empirical Study I was conducted under the S3 Project; see Chapter 4: Research Process. The study detailed in this chapter has been published; therefore, the results are identical to those previously published.

Pickering SP, Robertson ER, et al. Compliance and use of the World Health Organization checklist in UK operating theatres. British journal of surgery. 2013;100(12):1664-70.

5.3 Introduction

This study focused on real-time use of the WHO SSC. The background of the WHO SSC is detailed in *Chapter 3: A Scoping Review*. This study is based on pre-intervention phase data which was collected under the S3 Project. As part of the S3 Project, observation of WHO SSC time-out and sign-out sections was defined as an outcome measure.

This study was specifically aimed to observe WAD in practice, establishing real-world adherence to the WHO SSC in operating theatres in UK NHS hospitals. Compliance of the WHO SSC is mandatory in the UK, and reported high compliance rates demonstrate successful checklist use, thereby matching WAI. Therefore, this study investigates theatre team performance of the WHO SSC time-out and sign-out sections via direct observation. Performance is measured by attempt of the WHO SSC time-out and sign-out sections and the quality of performance, which are recorded in 3 parameters:

1. All information communicated
2. All team present
3. Active participation

5.4 Research Question

The following research question was investigated:

RQ2: What is the current level of compliance to the WHO SSC in UK hospital operating theatres practice?

5.5 Aim and Objectives

5.5.1 Aim

The aim of this study is to advance the understanding of how the WHO SSC is used in practice by directly observing the checklist in use by theatre team members in the operating theatre, as an evidence-based outcome of WAD for surgical checklists in use.

5.5.2 Objectives

5.5.2.1 Primary objectives

- I-O-1: to assess theatre team members' attempts at performing the WHO SSC time-out and sign-out sections.
- I-O-2: to assess theatre team members' quality of performance for WHO SSC time-out and sign-out sections.

5.5.2.2 Secondary objectives

- I-O-3: to assess if there is a difference in theatre team members' performance for WHO SSC time-out and sign-out sections between NHS Trusts.
- I-O-4: to assess if there is a difference in theatre team members' performance for WHO SSC time-out and sign-out sections between surgical specialties.
- I-O-5: to assess if there is an association between WHO SSC time-out quality of performance and the sequential attempt of the sign-out.
- I-O-6: to assess performance time of conducting WHO SSC time-out and sign-out sections.
- I-O-7: to assess if there is an impact of leader on the quality of performance for the WHO SSC time-out section.

5.6 Methodology

5.6.1 Introduction

An observational study, via direct observation, was selected as the most appropriate methodological approach. This approach is the least intrusive method to evaluate individual and team performance in a work setting. The rationale for this method is based on the operating theatre being a busy and dynamic environment, with numerous theatre team members present for each surgical operation. Additional non-theatre team personnel present in the operating theatre should ideally not intervene with the flow of the

surgical procedure or theatre team duties. Therefore, by-stander observation was selected as the most appropriate approach for real-time, uninterrupted data collection of theatre team performance in the operating theatre.

5.6.2 Data Collection Locations

Data collection was conducted at five hospitals within three UK NHS Trusts, consisting of:

- one district general hospital
- three teaching hospitals
- one tertiary referral centre.

5.6.3 Data Collection Period

The period of data collection was between January 2011 and September 2012.

5.6.4 Research Team Composition

The S3 project research team consisted of a principal investigator and a co-investigator, a research team lead, and four full-time research associates: two based at *Oxford University* and two based at *Warwick Orthopaedics, Warwick Medical School*.

Each of the four full-time research associates was offered the opportunity to undertake a postgraduate research degree at their respective university and to utilise S3 project data towards fulfilment of their research degrees. As one of the research associates, I registered for a PhD in Medical Sciences at *Warwick Medical School*. I selected to lead part of the S3 project related to use of the WHO SCC due to my extensive experience in checklist use in aviation and my aim to advance knowledge of checklist use in surgery.

Additional part-time research assistants were recruited as required to support the S3 project core research team, specifically for the data collection phase as this was very labour intensive. Therefore, the research team responsible for data collection consisted of 4 core team members and 2 part-time team members. All researchers were assigned to form three observer teams. Each observer team was mixed discipline, consisting of two researchers from different disciplines: one observer with an HF background and one observer with a surgical background (a surgical trainee). My role as part of the research team was as an HF specialist. I was paired with one of the surgical trainees to form an observer team. We were based at *Warwick Medical School* to cover the hospitals in close proximity participating in the S3 Project.

The other two observer teams were based at *Oxford University* to cover the hospitals in close proximity participating in the S3 Project. Throughout the study data collection period, observer teams rotated periodically between their respective bases and assigned hospital sites to reduce observer bias and complacency; this was also aimed to reduce overfamiliarity between the observers, the theatre team members under observation, and the local theatre processes at their assigned hospital sites. An observation schedule was designed to spread the observation days at each hospital site to share the workload between observer teams.

A statistician was also employed on the S3 project to lead data analysis.

5.6.5 Observer Training

All observers were trained in the data collection methods of direct observation and recording of data. Each of the research associates had no prior experience in each other's domain of expertise. Therefore, cross domain training was provided in preparation for the study in conjunction with training in observation techniques in surgical settings. The HF observers received training which familiarised them with surgical procedures and the

surgical environment; the surgical trainee observers received training which familiarised them with HF principles and practices.

Observer training was conducted over a two-month period, prior to the data collection phase of the study. All training sessions were led by the research team lead who was an HF expert with extensive experience in observing surgical teams at work in the operating theatre. Training was first received in a class-based environment away from the operating theatre, then continued in the operating theatre during real-time surgery. Class-based training sessions consisted of lectures explaining core principles and practices in HF and how they relate to observing theatre teams in the operating theatre. Material was collected by the lead researcher and was presented in PowerPoint presentations with literature references for review. The content of the literature was supported by video recordings showing example scenarios of theatre teams at work in the operating theatre, represented in a simulated setting. The researchers discussed the content of scenarios with regard to HF performance characteristics and learnt how one would observe and interpret these via direct observation. The human performance characteristics were based on those defined in the Oxford non-technical skills system referred to as '*Oxford NOTECHS II*'.^{30,279} This is a rating scale developed to evaluate operating team performance on the parameters below:

- Leadership and management: leadership, maintenance of standards, planning and preparation, workload management, authority and assertiveness;
- Teamwork and cooperation: team building / maintaining, support of others, understanding team needs, conflict solving;
- Problem-solving and decision-making: definition and diagnosis, option generation, risk assessment, outcome review;
- Situation awareness: notice, understand, think ahead.

In-theatre training consisted of several sessions, whereby the observers in their paired teams were accompanied by the research team lead. During

these sessions, the research team lead highlighted behaviour and relevant performance characteristics shown by the theatre team members related to those discussed in the class-based lectures. In addition, other key aspects of the surgical process were highlighted, such as equipment issues, communication issues etc. To enhance the knowledge of the HF specialists, the surgical trainees also provided ad-hoc mentoring to explain aspects of the surgical procedure as required. These in-theatre training sessions spanned a one-month period and were aimed to train the observers in the required techniques to observe, interpret, and accurately capture observation data. Training took place at two out of the five recruited hospitals.

5.6.6 Data Collection Material

During the training period, all researchers received training on data collection methods, firstly via collaboratively developing the data collection material, then trialling the tools in practice sessions.

Data collection material was created in the form of process maps referred to as 'protocol booklets'²⁸⁰ to record all observational data for the S3 Project; process maps were based on the work by Lingard et al.³⁴ Within the protocol booklet was a dedicated section for the WHO SSC time-out and sign-out performance data to be captured real-time.

A protocol booklet was designed specifically for each type of surgical procedure under observation, which detailed key milestones in the surgical procedure. The aim of this was to ensure that the observers could track progress of the surgical procedure and record data within these pre-defined milestones as 'phases' of the surgical operation. The protocol booklets were primarily created by the surgical trainee research team members as they were most familiar with the technical steps of each surgical procedure under observation. The draft protocol booklets for each surgical specialty were reviewed and edited by the remaining research team members to ensure

usability of the layout, familiarity with the content, and accuracy of non-surgical content. A scanned copy of the hip arthroscopy protocol booklet can be found in *Appendix F – S3 Project Hip Arthroscopy Protocol Booklet*.

Protocol booklets were the main data collection tool used in this study. The size of the protocol booklet was purposely made small to ensure discrete data capture, with enough space to record pre-determined data points and freehand notes, if required.

5.6.7 Observation Data Points

The complete WHO SSC consists of 3 sequential sections:

- Section 1: sign-in
- Section 2: time-out
- Section 3: sign-out.

The research team elected not to observe Section 1: sign-in, as this was considered difficult to observe due to it being completed in a small induction (anaesthetic) room, adjacent to the operating theatre. In order to consider the patient's privacy and due to the confined space, data was not collected on this section. This methodological approach is supported by similar observation studies whereby the sign-in was excluded from data collection due to logistical issues. Only a small number of studies was identified as including sign-in data (7 in total which were identified in the scoping review). Reporting of these studies referred to the observation of sign-in, yet only one study specifically mentioned the location of where the sign-in process was administered; in this study, the hospital had adapted the sign-in to allow administration in either the pre-anaesthetic room or the operating theatre.²⁸¹ In another study, sign-in data was reported as collected with no further evaluation due to logistical issues.²⁸² It was understood that this would limit a full data set on WHO SSC performance; however, a minimally intrusive approach was conclusively considered more important by the research team.

The protocol booklets were organised to correspond to the remaining two sections of the WHO SSC: time-out and sign-out. Section 2: time-out and Section 3: sign-out are designed to be performed in the main operating theatre, which is a larger room, enabling more space to accommodate the two observers. The observer team was present in the operating theatre throughout the surgical procedure in order to observe multiple data points for the S3 Project and performance of the WHO SSC time-out and sign-out sections. The time-out must be performed prior to the first incision, and the sign-out must be performed after the surgical procedure is completed. In order to capture data on these two sections, the observers attended full operating lists and consecutive surgeries to cover a representative sample of surgical cases.

A variety of surgical specialties was included in the case selection, as detailed in *Table 5-1: Surgical Case Mix Selected for Observation* below.

Table 5-1: Surgical Case Mix Selected for Observation

Surgical Specialty	Types of operation
Elective Orthopaedics	Primary and revision knee and hip arthroplasty and arthroscopic procedures.
Trauma Orthopaedics	Manipulation of fractures and dislocations under anaesthetic, open reduction, and either internal fixations or hemi-arthroplasty procedures.
Vascular Surgery	Arterial bypass, endarterectomies, and hernia repair.
Plastic Surgery	Excision of benign and malignant lesions with a range of closure techniques including free flaps and upper limb and nerve surgery.

Elective orthopaedics was the primary surgical specialty observed in this study as this was the main surgical specialty performed at the participating hospitals. Trauma orthopaedic surgery was included; however, observations were kept to a minimum because of the non-standard nature of this type of surgery, which does not often follow a pre-defined surgical process. Vascular and

plastic surgeries were added to compare WHO SSC performance between different surgical specialties.

The observer team assessed time-out section and sign-out section attempts as a primary performance measure, i.e. a 'yes' for a positive check if that section of the checklist was attempted by a member of the theatre team, and a 'no' for a negative check if that section of the checklist was not attempted. The role of this theatre team member was also recorded, i.e. anaesthetist, surgeon, nurse.

In addition, the quality of performance by the theatre team was also assessed for the WHO SSC time-out and sign-out sections on 3 quality parameters:

1. All information communicated:

This relates to whether each point on the relevant section of the WHO time-out and sign-out had been communicated, i.e. read aloud by one theatre team member and verbally answered by the relevant theatre team member.

2. All team present:

This relates to whether all required theatre team members, i.e. at least one representative from the anaesthetist, surgeon, and nursing teams, were present in the operating theatre during performance of the WHO SSC time-out and sign-out section.

3. Active participation:

This relates to whether there was active participation by the theatre team members during performance of the WHO SSC time-out and sign-out sections, i.e. whether questions were asked verbally by the team member performing the checklist and whether responses were received verbally by the relevant member of the theatre team.

Each observer used a protocol booklet corresponding to the operation being performed to record their observations individually. The two observers in the

observer team did not confer during the surgical procedure and often stood in a different part of the room. An additional benefit of standing in different parts of the operating theatre was for each observer to gain a different vantage point within the operating theatre. Observers were trained to observe the same parameters; on occasion observers were able to capture different aspects of the surgical process that the other observer could not see from their position. This was neither considered a limitation to direct observation nor assessed as having a negative impact on the data collection method; it was considered necessary to ensure the overall quality of data collection as a benefit of having two observers.

Data collection commenced when the patient entered the operating theatre and ended when the patient left the operating theatre to be moved to the recovery area.

5.6.8 Methods Validation

After each surgery was completed, the observers immediately compared their data and notes captured in the protocol booklet in order to calibrate and confirm accuracy of the real-time data collected. Any discrepancies were discussed verbally, and consensus was reached real-time. This task was completed during the phase when the operating theatre was being prepared for the next operation.

Inter-observer reliability was not tested, which is considered a limitation of the study. However, researchers did mix across observer pairs for a small number of observation sessions to ensure calibration of the data collection approach conducted by each observer. The research team acknowledged that testing for inter-observer reliability would have strengthened the study design.

5.6.9 Treatment of Raw Data from Observations

Post data collection, raw data from the protocol booklets was transferred manually to a web-based programme. This was designed to resemble the

fields of the protocol booklet, including drop-down menus where appropriate. Data entry was completed by the respective observer team who had observed the operation. The observers had first-hand experience of observing the operation, and therefore, additional staff were not recruited for data entry to ensure that no data entry errors would be made from handwritten notes by others.

Data entry activity was conducted as close to the observed operation as practicable to ensure that recall of the operation details was not significantly degraded; however, daily data entry was not possible due to the lengthy time commitments to observe a full operating list, which often spanned from 7am to 7pm.

Raw data was extractable from the web-based programme in excel format for statistical analysis.

5.6.10 Consent to Participate

5.6.10.1 Theatre team members (anaesthetist, surgeon, nurse)

All theatre staff recruited to participate in the study were fully briefed by the researchers and consented to participate under ethical clearance from the *Oxford A Ethics Committee* (REC:09/H0604/39). Details of the study aims were presented to each potential participant. Consent was obtained outside of the operating theatre prior to the start of the operation, when practicable. If a new member of the operating team unexpectedly joined the operating theatre, a real-time briefing was provided, and consented on the spot. Consent to participate was given by one hundred percent of the briefed participants.

5.6.10.2 Patients

The research team had no interaction with the patients. Patient information was known to the research team via the patient lists; however, all patients were kept anonymous and were mostly under anaesthetic when entering the operating theatre. In addition, the observers wore surgical clothes and masks

as a requirement for operating theatre attire and in order to blend in with other theatre team members in the operating theatre. Therefore, patient consent was not required by the ethics committee. All data was de-identified to ensure patient anonymity. Data was stored on *Oxford University* and *Warwick Medical School* password protected computers and was only accessible by the S3 Project research team.

5.7 Results

As previously stated, the results of this study have been published. Therefore, the data, tables, and graphs are a direct copy of those published in Pickering et al.¹⁴⁴ The S3 Project statistician conducted all S3 Project statistical analysis (acknowledged in *Declarations*, p12), including those presented in this study. All stages of analysis were discussed with the S3 research team members, edited as required, and collaborative decisions were made related to final selected analyses. I, as the lead author of the research publication, completed the final review and acceptance of the statistical analysis for the results of this study.

5.7.1 Statistical Analysis

In this study, descriptive statistics are presented. Continuous data are summarised by the median, interquartile range (i.q.r.), and range. Binary data are summarised as proportions. Comparison of proportions was performed with the χ^2 test; $P < 0.050$ was considered statistically significant. All statistical analysis was performed in R version 2.15.3.²⁸³

5.7.2 Study Characteristics

A total of 294 operations were observed in a range of surgical specialties. The surgical specialty, associated types of operation, and numbers of observed operations in each surgical specialty are shown in *Table 5-2: Summary of Observed Operations* below.

Table 5-2: Summary of Observed Operations

Surgical specialty	Types of operation	Number, n
Elective Orthopaedics	Primary and revision knee and hip arthroplasty and arthroscopic procedures	211
Trauma Orthopaedics	Manipulation of fractures and dislocations under anaesthetic, open reduction, and either internal fixations or hemi-arthroplasty procedures	16
Vascular Surgery	Arterial bypass, endarterectomies and hernia repair	45
Plastic Surgery	Excision of benign and malignant lesions with a range of closure techniques including free flaps and upper limb and nerve surgery	22

5.7.3 WHO SSC Time-out and Sign-out Section Attempts in 294 Operations Across 5 UK Hospitals

During the study period, 294 operations were observed. The WHO SSC time-out section was attempted in 257 operations out of the 294 operations observed. The WHO SSC sign-out section was attempted in 26 operations out of the 294 operations observed. *Table 5-3: Proportion of Operations with Attempts at WHO SSC Time-out and Sign-out in 294 Operations Across 5 Hospital Sites* below shows the spread of descriptive data across the observed surgical specialties and hospital sites.

Table 5-3: Proportion of Operations with Attempts at WHO SSC Time-out and Sign-out in 294 Operations Across 5 Hospital Sites

	Site A	Site B	Site C	Site D	Site E	Total for specialty
Time-out attempted						
Elective Orthopaedics	92 of 101 *(91.1)	11 of 26 (42.3)	53 of 54 (98.1)	27 of 30 (90.0)	-	183 of 211 (86.7)
Trauma Orthopaedics	-	-	16 of 16 (100.0)	-	-	16 of 16 (100.0)
Vascular surgery	-	15 of 21 (71.4)	-	-	24 of 24 (100.0)	39 of 45 (86.7)
Plastics surgery	19 of 22 (86.4)	-	-	-	-	19 of 22 (86.4)
Total per site	111 of 123 (90.2)	26 of 47 (55.3)	69 of 70 (98.6)	27 of 30 (90.0)	24 of 24 (100.0)	257 of 294 (87.4)
Sign-out attempted						
Elective Orthopaedics	4 of 101 (4.0)	2 of 26 (7.7)	3 of 54 (5.6)	0 of 30 (0.0)	-	9 of 211 (4.3)
Trauma Orthopaedics	-	-	0 of 16 (0.0)	-	-	0 of 16 (0.0)
Vascular surgery	-	0 of 21 (0.0)	-	-	17 of 24 (70.8)	17 of 45 (37.8)
Plastics surgery	0 of 22 (0.0)	-	-	-	-	0 of 22 (0.0)
Total per site	4 of 123 (3.3)	2 of 47 (4.3)	3 of 70 (4.3)	0 of 30 (0.0)	17 of 24 (70.8)	26 of 294 (8.8)

* 'n' of 'n' represents number of operational cases whereby an attempt was made to complete the WHO SSC section, out of the total number of operations observed for that surgical specialty.

**The figure in parenthesis shows the percentage of this data.

Time-out attempts were made at all sites, although time-out attempts at Site B were much lower than observed at other sites. There was a statistically significant difference between hospital sites in terms of their frequency of time-out attempts ($X^2(df=4)=49$, $p < 0.001$).

Sign-out attempts were low across Sites A, B, C, and D. Sign-out attempts were observed as much higher at Site E (71%) than observed at other sites (ranging from 0% to 4% total per site). There was a statistically significant difference between hospital sites in terms of their frequency of sign-out attempts ($X^2(df=4)=70$, $p < 0.001$).

A high number of time-out attempts were observed across all surgical specialties. There was no statistically significant difference between surgical specialties in terms of their frequency of time-out attempts ($X^2(df=3)=4$, $p=0.218$).

A low number of sign-out attempts were observed across all surgical specialties. Sign-out attempts were observed as higher in vascular surgery (38% total per specialty) than observed in other surgical specialties (ranging from 0% to 4% total per specialty). No sign-out attempts were observed in trauma orthopaedic surgery or plastic surgery. There was a statistically significant difference between surgical specialties in terms of their frequency of sign-out attempts ($X^2(df=3)=41$, $p < 0.001$). Reported statistical differences may be explained by differences in performance between hospital sites rather than differences between surgical specialties. In particular, Site E had a higher performance of sign-out attempts (71%), which was observed in vascular surgery, compared to sign-out performance at all other sites across surgical specialties (ranging from 0% to 8%).

5.7.4 Quality of Performance of the WHO SSC Time-out and Sign-out Sections

The quality of performance of the time-out and sign-out sections was assessed. Figure 5-1: *Quality of Performance of the Time-out and Sign-out Process Observed Across All 5 Hospital Sites* below shows a graphical representation of the attempt frequency and associated score for each of the 3 quality parameters.

The data in *Figure 5-1* shows that overall the quality of performance was suboptimal (below 100%) in the 294 observed operations.

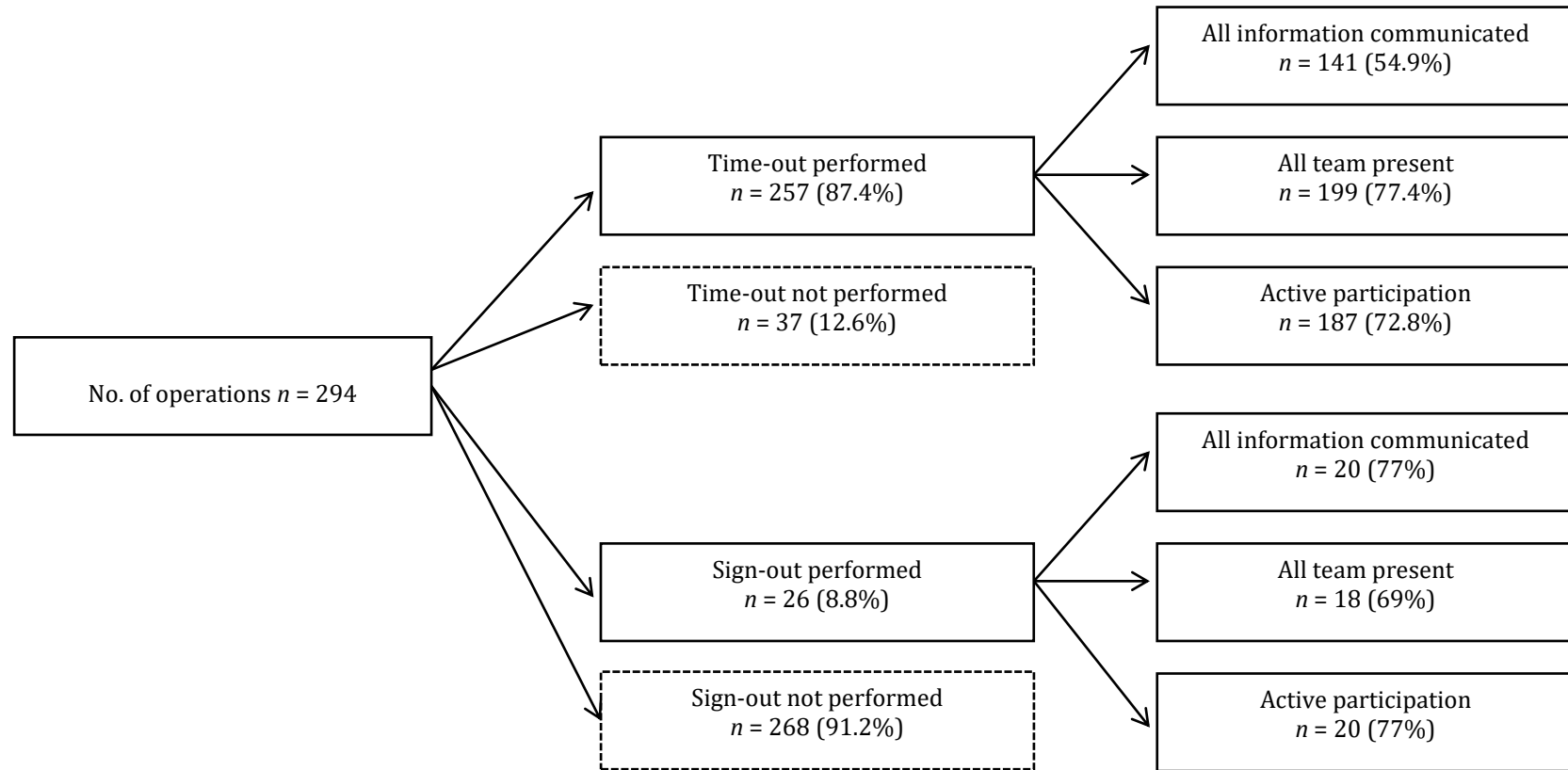


Figure 5-1: Quality of Performance of the Time-out and Sign-out Process Observed Across All 5 Hospital Sites

5.7.5 Quality of Performance of the Time-out Section

Figure 5-1 above shows the success scores for each quality parameter in the observed cases when a time-out was attempted. The quality parameter 'all information communicated' had the lowest performance, with just over 50% of theatre teams communicating the full content of the time-out section. Performance related to the other two quality criteria, 'all team present' and 'active communication', was over 70% in both cases.

5.7.6 Quality of Performance of the Sign-out Section

Figure 5-1 above shows the success scores for each quality parameter in the observed cases when a sign-out was attempted. In the small number of sign-out attempts, 26 attempts out of the 294 surgical cases observed, performance in the 3 quality parameters ranged between 69-77%.

5.7.7 WHO SSC Time-out and Sign-out Attempt Frequency and Associated Quality of Performance

Figure 5-2: Performance of the WHO SSC Time-out Process (Figure 5-2a) and Sign-out process (Figure 5-2b) below graphically presents the WHO SSC time-out (Figure 5-2a) and sign-out (Figure 5-2b) attempt frequency and associated success score for the 3 quality parameters, providing an overview of performance of the WHO SSC process for these two sections.

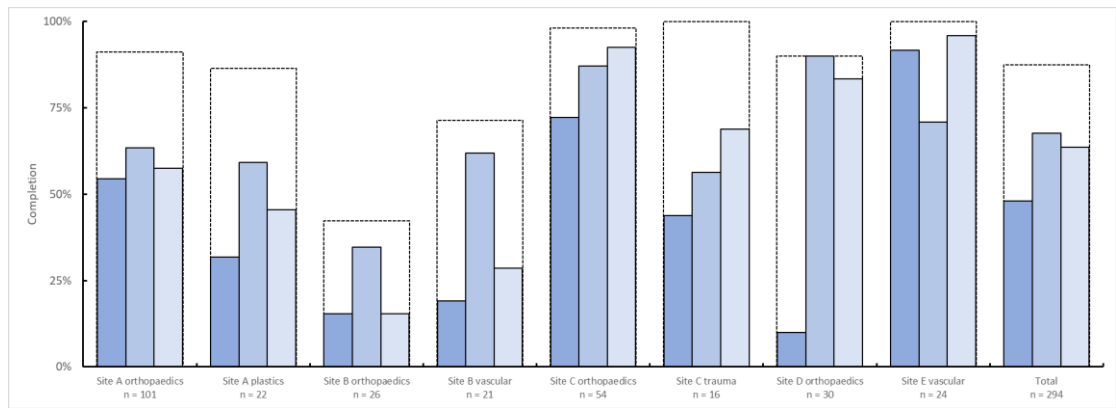


Figure 5-2a: Time-out

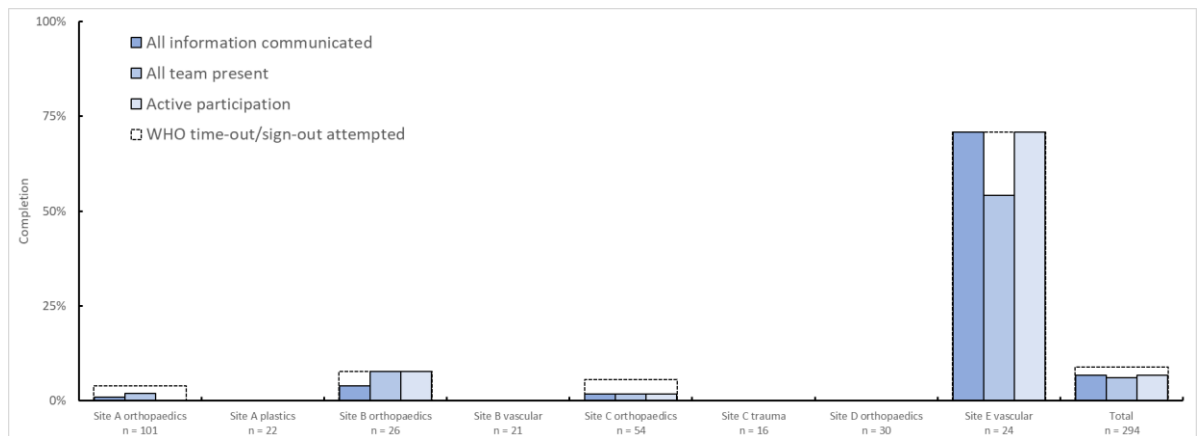


Figure 5-2b: Sign-out

Figure 5-2: Performance of the WHO SSC Time-out Process (Figure 5-2a) and Sign-out process (Figure 5-2b)

5.7.7.1 Performance of the WHO SSC time-out process

Overall, *Figure 5-2a* above shows that:

- successful scores for all 3 quality parameters are low;
- ‘all information communicated’ shows the lowest performed quality parameter;
- Sites B and D are particularly low for ‘all information communicated’; and
- orthopaedics at Site C and vascular at Site E have the highest success score for ‘all information communicated’.

Therefore, performance of the WHO SSC time-out process is suboptimal across the hospital sites and the observed surgical specialties.

5.7.7.2 Performance of the WHO SSC sign-out process

Overall, *Figure 5-2b* above shows that:

- successful scores for all 3 quality parameters are extremely low;
- Site C has high success scores during time-out attempts on the 3 quality parameters but extremely low performance during sign-out; and
- Site E has the highest success scores on all 3 quality parameters for the sign-out process.

Therefore, performance of the WHO SSC sign-out process was suboptimal across the participating hospital sites and the observed surgical specialties. Site E performed better than all other hospital sites.

5.7.8 Association Between Time-out Quality and the Sequential Attempt of a Sign-out

Time-out attempts were observed in 257 operations out of a total of 294 observed operations; the sequential attempt of the sign-out section was observed in 26 of those 257 operations. Therefore, there was no occasion observed whereby a sign-out section was attempted without a pre-existing time-out section attempt.

Table 5-4: Time-out Quality Parameter Scores and Associated Proportion with Sign-out Attempt below shows the scores of the observed WHO SSC time-out quality parameters. The table provides the scores when the WHO SSC time-out:

- was not attempted;
- was attempted but no quality parameters were scored;
- when one, two, or all three quality parameters were scored; and
- was attempted with the associated sign-out attempt, represented as a proportion of the total time-out attempts.

Table 5-4: Time-out Quality Parameter Scores and Associated Proportion with Sign-out Attempt

	Time-out compliance (n=294)	Sign-out compliance (n=26)
All parameters	99 *(33.7)	19 of 99 (19.2)
Two of three parameters	88 (29.9)	6 of 88 (6.8)
One of three parameters	54 (18.4)	1 of 54 (1.9)
No parameter	16 (5.4)	0 of 16 (0.0)
WHO time-out not attempted	37 (12.6)	0 of 37 (0.0)

* Values in parentheses are percentages.

When assessing performance success across the 3 quality parameters, *Table 5-4* above shows that approximately only one third of observed time-out attempts resulted in a success score for all 3 parameters (33.7%). In the observed cases when a time-out was attempted, 5.4% did not score on any of the quality parameters. In addition, only 19.2% of the observed sign-out attempts resulted in a successful score of quality.

In 294 observed operations, there were 37 operations whereby a time-out was not attempted (12.6%) and 257 operations whereby a time-out was attempted (87.4%).

In 294 observed operations, 99 WHO SSC time-out attempts scored on all 3 quality parameters (33.7%). Of these 99 WHO SSC time-out attempts, only 19 had an associated sign-out attempt (19.2%).

In 294 observed operations, 88 WHO SSC time-out attempts scored on 2 out of 3 quality parameters (29.9%); the quality parameter 'all information communicated' was most likely to be missing. Of these 88 WHO SSC time-out attempts, only 6 had an associated sign-out attempt (6.8%).

In 294 observed operations, 54 WHO SSC time-out attempts scored on 1 out of the 3 quality parameters (18.4%); the most frequently scored quality

parameter was 'all team present'. Of these 54 WHO SSC time-out attempts, only 1 had an associated sign-out attempt (1.9%).

In 257 observed operations with a WHO SSC time-out attempt, 16 did not score for any of the quality parameters (5.4%). Of these 16 WHO SSC time-out attempts, none had an associated sign-out attempt (5.4%).

5.7.9 Performance Time for Time-out and Sign-out Process Completion

Performance time was measured from initiation of the first communication point on the checklist section (time-out or sign-out) until the last communication point of the checklist section (time-out or sign-out) was completed, i.e. when a response was given to the last question. The theatre clock was used by both observers to record the performance time for time-out and sign-out process completion.

5.7.9.1 Performance time for the time-out section

The median time taken to perform a time-out section was 60 seconds (i.q.r. 55-80 seconds, range 10-240 seconds).

5.7.9.2 Performance time for the sign-out section

The median time taken to perform a sign-out section was 60 seconds (i.q.r. 50-60 seconds, range 30-180 seconds).

The results show an equivalent median time to complete both sections, with differences in i.q.r and range.

5.7.10 Impact of Leader on Quality of Performance of the WHO SSC Time-out

Any of the theatre team members could lead the WHO SSC time-out process (i.e. anaesthetist, surgeon, or nurse). There was no significant impact on the quality of performance related to which theatre team member led the WHO SSC time-out section; see *Table 5-5: Quality of Time-out by Specialty of Time-out Lead* below for details.

Table 5-5: Quality of Time-out by Specialty of Time-out Lead

	Anaesthesia (n = 40)	Surgical (n = 59)	Nursing (n = 149)	P*
All information communicated	19(47.5)	34 (57.6)	84 (56.4)	0.554
All team present	36 (90.0)	46 (78.0)	114 (76.5)	0.172
Active participation	33 (82.5)	38 (64.4)	112 (75.2)	0.111

Values in parentheses are percentages. * χ^2 test.

As sign-out was rarely attempted, this quality measure was not analysed as the sample size was considered too low to show any relevant results.

5.8 Discussion

In this section, the findings of the study will be discussed, briefly exploring how they relate to other research findings and the contribution to existing knowledge of WHO SSC use and compliance. Further discussion with regard to checklist use in surgery is presented in *Chapter 7: Discussion and Conclusions*. This includes suggested future work and the strengths and limitations of this study.

5.8.1 Overview of the WHO SSC Use in UK Hospitals

The aim of this study was to investigate theatre team members' performance of the WHO SSC use via direct observation, both in attempting the time-out

and sign-out sections, and quality of performance when attempted. The findings of this study suggest that there are issues with time-out and sign-out adherence: time-out was typically attempted, although the quality of performance varied. Sign-out was rarely attempted, although on the occasions it was attempted, it was always associated with a time-out attempt. Therefore, the WHO SSC does not always work in practice as imagined, bringing successful use and the value of mandatory compliance reporting into question.

In its initial use, the WHO SSC was reported to demonstrate improvements in clinical outcomes.¹ However, the findings from this study indicate a decline in successful use in UK hospitals, as adherence to the WHO SSC was found to be an issue for the time-out and sign-out sections. These sections of the WHO SSC are not being used as expected, and therefore, previously reported safety benefits of checklist use may be impacted.^{171,284}

5.8.2 Observed WHO SSC Time-out and Sign-out Performance

The WHO SSC use is mandatory in UK hospitals and compliance targets are set to 100%; therefore, performance of the time-out and sign-out sections was expected to be near perfect. However, the findings of this study show a different reality of when the checklist is used in practice.

The following findings are presented to address primary objective I-O-1:

- to assess theatre team members' attempts at performing the WHO SSC time-out and sign-out sections.

The time-out was attempted in 257 of the 294 observed operations. At a minimum, time-out attempts were expected in all observed cases. No unusual circumstances were observed to prevent a time-out attempt; therefore, no objective evidence can be provided for the missing number (37) of time-out attempts.

The sign-out was attempted in a surprisingly low number of observed operations: a total of 26 of the 294 observed. This finding is concerning

considering the safety critical steps this final section of the WHO SSC contains. When the sign-out was attempted, it was always associated with a time-out attempt, indicating some association between the checklist sections. However, the large gap of missed sign-out attempts cannot be explained.

The sign-out should be performed after the surgical procedure has been completed and prior to the patient leaving the operating theatre. The sign-out section is relatively short in comparison to the other WHO SSC sections (sign-in and time-out), yet performance was consistently low across the hospital sites and the surgical specialties.

The findings of this study suggest that the sections of the WHO SSC are considered separate isolated components rather than a complete process, further illustrated by the small number of sign-out attempts. However, sign-in data was not collected in this study; therefore, a complete assessment of this perception is not possible, and conclusions cannot be formed. The literature on the WHO SSC compliance rates has limited data on adherence to the sign-in section. This may be due to the same logistical issues surrounding data capture in this confined space as determined in this study.

The benefits claimed for the WHO SSC¹ are reliant on checklists being performed reliably.⁷³ The *Safe Surgery Programme* and the WHO discouraged elimination of any safety step unless that safety step was incorporated into another process that would ensure its coverage and completion.^{10,91} When the WHO SSC was designed, no distinction was made between the three checklist sections with regard to differing levels of importance. The intention was for the WHO SSC to be performed as a whole and completed in its entirety. The positives of completing the checklist process to benefit patient outcomes are supported by de Vries.¹⁵⁴

However, observations suggest that theatre teams perceive little relationship between the three WHO SSC sections. This may be explained by the timings of each section. There is a lengthy disconnect between initiation of each of the WHO SSC sections, which are dependent on the length and complexity of the

operation process flow. In addition, in the UK, this may be amplified by the sign-in being performed in the induction room and the remaining sections (time-out and sign-out) being performed in the operating theatre. This physical disconnect may lead to a mental disconnect, which could create a barrier to successful checklist completion.

There is no conclusive evidence from the observations to support whether performance of the sign-out section was forgotten or intentionally missed. However, narrative data captured during the observations suggest that the sign-out was perceived to conflict with a particularly high stress and high workload period in the surgical flow. For example, at the end of an operation, each theatre team member is responsible for a series of tasks; completion of these tasks aims to ensure that the patient is transferred to recovery in an efficient and accurate handover. During this period, tasks are being performed in parallel to prepare the operating theatre for the next patient. Theatre team members frequently commented that “*there is no time and no-one available for sign-out.*” Possible related issues such as logistics were noted during the observations, e.g. the patient recovery area was external to the operating theatre, thus potentially creating a physical barrier to overcome when moving the patient and communicating with the recovery team. The design considerations applied to sign-out specify that it is intended to be performed at a natural ‘pause point’, yet findings suggest that this does not match with WAD in UK hospital daily practice.

Orthopaedic surgery has high patient turnover rates, which may be a contributing factor for theatre teams not performing the sign-out process due to strict time pressures. This may add additional pressure on the theatre teams to run a *time efficient list* with an aim to complete as many operations daily as practicable. This is supported by theatre team members’ comments referring to the checklist being an “*additional task,*” and, “*sign-out is too much for the team to manage at the time between one operation finishing and preparing for the next.*” The largest number of observed surgeries were orthopaedic cases; therefore, the issue of reduced performance may be amplified in this study due to the high rate of turnover.

The following findings are presented to address primary objective I-O-2:

- to assess theatre team members' quality of performance for WHO SSC time-out and sign-out sections.

To target the quality of performance when time-out and sign-out were attempted, 3 quality parameters were assessed. The measure was relatively simple with a 'yes' or 'no' score. A 'yes' score indicates satisfactory performance and a 'no' score indicates unsatisfactory performance. The quality parameters: 'all information communicated', 'all team present' and 'active participation' were selected to collectively capture the quality of performance, and thus, adherence to the WHO SSC section.

Of the total observed time-out attempts, satisfactory performance in all 3 parameters was found in 99 of 257 operations, representing 38.5%. This figure represents surprisingly low-quality adherence. Administrative audit data completed at each site during the study period was checked to identify any anomalies resulting in suboptimal performance; audit data reported high levels of compliance of over 95%. This presents a disconnect between checklist use in practice and reported compliance by the theatre teams.

The weakest performance parameter was found to be '*all information communicated*'; this was an important finding as communication is considered one of the key benefits of checklist use.^{20,34,285,286} The time-out was designed to support communication within the team by facilitating information sharing between team members. In its early implementation, Lingard et al comment that the WHO SSC could be an efficient tool to aid the exchange of information between theatre team members and has the potential to enhance team cohesion.^{20,34,287}

Effective and efficient communication in team working has been documented as a key success factor. Communication failures have been reported to have an impact on theatre team performance and patient safety. Lingard et al later explain that communication failures increased the cognitive load of theatre team members, interrupted the surgical flow, and increased tension between

the theatre team members, thereby supporting checklists as a form of standard communication.²⁰

However, the findings of this study suggest a lack of standardisation in executing the checklist, mostly due to observed variation in the quality of performance. This performance factor has the potential to impact the benefits of the checklist for standardised communication between the theatre team members. Biffl et al also found widespread variation with the WHO SSC performance, which impacted compliance.²⁸⁸ The observed performance variations expand understanding of how the WHO SSC is used in practice and represents supporting evidence for substandard adherence to the checklist process.

During observations, concurrent tasks and multiple conversations were captured during performance of the WHO SSC time-out section. On numerous occasions when the WHO SSC time-out was being performed in the operating theatre, the consultant surgeon was recorded as physically present but was conducting desterilisation tasks in an adjoining side room. All other theatre team members were present in the operating theatre, which may have been perceived to represent a physical barrier, potentially hindering team cohesion and effective communication of time-out information. When observing and recording performance parameters such as 'all team present', these are important findings to report. In this situation, the score would have been 'yes' but the accuracy of that score does not capture the context reality; therefore, finer granularity definitions would be beneficial in future work. In these cases, the observation teams were trained to record the 'yes' or 'no' score and to make a brief note of the contextual circumstances. The S3 Project generated a vast amount of contextual data, which has not been treated to date. Retrospective analysis of the observation data would further illustrate what is happening during checklist use in practice and how this differs or supports imagined checklist use in the operating theatre.

In a large number of observed operations (a total of 294 observed), the number of sign-out attempts was exceptionally low (26 out of 294); therefore, it was

considered that any further analysis with regard to the quality of performance would give a misleading account of performance. The findings indicate that the WHO SSC sign-out is mismatched with operating theatre practice in the UK. An investigation into perceptions and culture may expand explanation for this finding.¹⁴⁴ However, this issue is not confined to the UK NHS as similar findings have been reported in the USA. A state-wide survey in Colorado, USA, indicated that use of the WHO SSC was inconsistent regardless of it being used in standard practices in hospitals across the state.²⁸⁹

Time-out attempts were observed in 257 operations out of a total of 294 observed operations. The sequential attempt of the sign-out section was observed in 26 of those 257 operations. Interestingly, it was expected that performance of the sign-out section would have been higher during the period of observations. Therefore, further investigation is warranted to understand why adherence was so poor for the sign-out process. An ethnography study investigating theatre teams' perceptions may advance understanding of these findings, as would a focused observation study of context to identify competing demands and other issues during the practical use of the sign-out section.

5.8.3 Findings Related to Differences Between UK NHS Trust Hospitals

The following findings are presented to address secondary objective I-O-3:

- to assess if there is a difference in theatre team members' performance for WHO SSC time-out and sign-out sections between NHS Trusts.

There was a statistically significant difference between hospital sites in terms of their frequency of time-out attempts ($X^2(df=4)=49$, $p < 0.001$). There was a statistically significant difference between hospital sites in terms of their frequency of sign-out attempts ($X^2(df=4)=70$, $p < 0.001$).

The 5 hospital sites participating in the study were all based in UK NHS Trusts; therefore, no variance was expected. Specifically, performance differences

would not be anticipated for attempting the WHO SSC time-out and sign-out based on UK-wide mandatory targets of 100% compliance. In addition, no economical differences were expected between the participating hospital sites. This study does not objectively determine why significant differences in time-out and sign-out performance were found between NHS hospital sites. Observations limited exposure to any factors that would suggest a deviation from the norm related to the region of the UK. However, this finding could suggest that inter-hospital differences were potentially the result of organisational culture variances at the local level. Research highlighting barriers to the success of the WHO SSC have identified organisational and cultural factors as a contributing factor.⁴³ Other studies on checklist implementation in high-income countries suggest that challenges to compliance are linked to organisational safety culture.^{34,184,229} Organisational safety culture may reside at the local level and inter-hospital differences may be due to local modification of the WHO SSC; WHO guidance encourages local modification of the WHO SSC.¹⁰ However, in the UK NHS hospitals, local modification is discouraged, and NHS hospitals must use an adapted version of the WHO SSC in England and Wales.⁴³ Therefore, no objective evidence via observations can be given to support this difference. The reasons for this are likely very complex and multifactorial.

A possible contributing factor noted during observations at hospital site A was the method to record completion of the time-out section. Signatures were recorded electronically, whereas in all other hospital sites (B-E), signatures were manually recorded on a paper version of the WHO SSC. A relationship between performance and the method of reporting checklist completion cannot be determined. This finding does not advocate for electronic checklist versions over paper-based versions; however, it does contribute evidence for the complexity of checklist use and the inconsistencies with checklist use.

Recording completion of the WHO SSC is considered a type of *self-audit*, which is typically the responsibility of one theatre team member. Incorrectly recording completion of the WHO SSC may lead to unreliable audit data. Gagliardi et al found that the WHO SSC was often documented as complete,

which was an inaccurate report when compared to observed inconsistent use of the checklist.²⁹⁰ At sites where completion of the checklists was paper based, these were archived in the patient's notes after completion of the operation. At the one site where checklist use was confirmed with an electronic signature, the accompanying paper checklist was destroyed at the end of the operation, resulting in lost evidence of aspects related to the quality of performance and no paper audit trail to reference.

5.8.4 Findings Related to Different Surgical Specialties

The following findings are presented to address secondary objective I-O-4:

- to assess if there is a difference in theatre team members' performance for WHO SSC time-out and sign-out sections between surgical specialties.

There was no statistically significant difference between surgical specialties in terms of their frequency of time-out attempts ($X^2(df=3)=4$, $p=0.218$). There was a statistically significant difference between surgical specialties in terms of their frequency of sign-out attempts ($X^2(df=3)=41$, $p<0.001$).

At each hospital site, not all surgical specialties were observed due to pragmatic reasons of surgical case availability, i.e. on observation days not all surgical specialties had a surgical case mix with an even spread of operations. Therefore, data collection related to surgical specialty was difficult to plan in advance of scheduled observation days. In addition, elective orthopaedic surgery was the highest observed specialty at the participating hospitals. Reported statistical differences for sign-out performance may be explained by differences in performance between hospital sites rather than differences between surgical specialties; further supporting the potential of organisational cultural issues at the local level.

5.8.5 Findings of Association Between Time-out Quality and Sign-out Attempt

The following findings are presented to address secondary objective I-O-5:

- to assess if there is an association between WHO SSC time-out quality and the sequential attempt of the sign-out.

The findings show that in general, as the quality declined in the WHO SSC time-out performance, the associated number of sign-out attempts also declined. However, the sign-out attempts were so low (26 out of 257 operations with a time-out attempt), it was considered that any further objective analysis would not show additional relevant findings.

5.8.6 Time-out and Sign-out Performance Time

The WHO SSC received extensive design considerations, ensuring that the checklist was usable within the surgical process flow. Specific attention was paid to the length of each section and the complete checklist, allowing coverage of the critical safety points and imagined execution at 'natural pause points' around operational workflow patterns.^{10,291}

The first edition of the WHO manual which accompanies the first edition of the WHO SSC states that other safety checks could be added as the checklist was not intended to be comprehensive; additional steps may be required for locally established procedures.²⁹² This is an important area to consider related to variances and design control. Additionally, there is potential for the length of the WHO SSC to be increased, which would deviate from the intent of its design.

The following findings are presented to address secondary objective I-O-6:

- to assess performance time of conducting WHO SSC time-out and sign-out sections.

The findings show that no difference was found in the median time taken to perform time-out and sign-out. Marginal differences were found in the i.q.r and range but not of significance:

- the median time taken to perform a time-out section was 60 seconds (i.q.r. 55-80 seconds, range 10-240 seconds).
- the median time taken to perform a sign-out section was 60 seconds (i.q.r. 50-60 seconds, range 30-180 seconds).

During development of the WHO SSC, the 3-part checklist was designed to be completed in 60-90 seconds in most situations,²⁹² with focus on only the critical items. The findings of this study indicate that in practice the WHO SSC sections take longer than as designed. Observed theatre team members commented that “*the time-out takes too long to perform.*” Observations found that the time-out took a maximum of 240 seconds to complete, and the median time taken to perform time-out was 60 seconds when uninterrupted. Therefore, considering the WHO SSC as a lengthy task is difficult to justify without a deeper understanding of the negative impacts on the surgical flow and perceptions of the theatre team members. Feedback from theatre teams is important to elicit any issues when using the checklist that may become barriers to successful implementation. Other research supports theatre team perceptions of a lengthy time-out; however, when measured in other studies, the average time to perform time-out was also found to be under one minute.²⁹³ In the small number of observed sign-out attempts, concurrent tasks were observed as always being conducted at the intended sign-out ‘pause point’, which may explain the increase in performance time for this short section.

A systems approach to understanding the WHO SSC in use would support a deeper investigation of issues that may impact checklist performance time in practice. Due to the dynamic nature of surgeries, the process flow is largely unpredictable, and an average WHO SSC performance time may not be achievable. Observations can advance contextual understanding of checklists in use and support their design to accommodate for fluid processes.

Adequate resources are a major factor to support checklist use in practice. During observations, theatre teams often commented on a lack of resources and a high staff turnover. Vijayasekar and Steele proposed that resourcing and training issues can both impact checklist use due to checklist fatigue, resulting in degrading performance and views of checklists as a tick box exercise, subsequently influencing judgement and decision-making.²⁹⁴

5.8.7 Impact of Leader on Time-out Performance

The following findings are presented to address secondary objective I-O-7:

- to assess if there is an impact of leader on the quality of performance for the WHO SSC time-out section.

The findings show that the discipline of the time-out leader had no significant impact on performance adherence, suggesting that there is no dominance or hierarchical influence on checklist adherence in UK hospitals.

The first edition of the WHO SSC manual provides direction on how to run a checklist and states that a single individual, often a circulating nurse, must be responsible for checking the checklist boxes.²⁹² The WHO SSC sections are typically led by nurses, as observed in this study. Surgeons very rarely lead time-out or sign-out as they are usually conducting sterilisation tasks or are already scrubbed at this time and cannot physically hold a paper checklist. However, representatives from each of the theatre team disciplines led the checklist at some point during this study period. The findings indicate that theatre teams in the UK are not driven by strict roles and responsibilities for checklist use, and there is no evidence to support the requirement for another approach. However, this is not the case in other studies, as Vats et al found that during performance of the WHO SSC, less senior members of the theatre team such as the scrub nurse felt reluctant to remind the surgeon or anaesthetist to perform the checklist.⁴³

Future work may determine if there is an impact on performance aspects related to active participation when a surgeon leads the WHO SSC. The lead surgeon is typically responsible for the patient, and the other theatre team members support with the same patient safety goal, thereby advocating for a flattened hierarchy to improve team cohesion.²⁹⁵

5.8.8 New Era of WHO SSC Compliance Issues

Mandatory compliance to the WHO SSC in UK NHS hospitals and reporting of high compliance rates indicate success with checklist use in the UK. However, the finding of this study contributes to the new era of research surrounding compliance issues with the WHO SSC.

After the launch of the WHO SSC in the healthcare industry, early research focused on the clinical benefits which were associated by use of the checklist in surgery. However, researchers have shifted their attention to investigating compliance through the real-world usage of the checklist in practice.^{44,286,296}

The suboptimal performance findings in this study are identified in similar studies. Rydenfält et al found compliance rate reporting issues with time-out attempts at 96% but quality of performance as low as 54%.²⁹⁷ Similarly, in a study by Cullati et al, the validation of the time-out section showed a mean percentage of 50% and in the sign-out section showed a mean percentage of 41%.²⁹⁸

Such studies begin to bridge the knowledge gap around checklist use in practice in surgical settings. This is important as it has been suggested that if the checklist is not being used as planned, this may weaken the expected benefits and subsequently negatively impact patient safety.^{44,48,171,172} Related to this, Rydenfält et al also add the concept of a *false sense of safety* whereby safety checks can be omitted when compliance issues are present because the checklist is thought to cover all relevant checks, imposing a new safety threat in the healthcare system.²⁹⁹

Beyond the disputes surrounding the WHO SSC, there is now an open and active debate regarding the value of surgical checklists. The WHO SSC defined ambitious aims, with significant improvement claims in the early years of implementation. However, there is currently no conclusive evidence to support that the WHO SSC was directly and solely responsible for the clinical improvements. It has been suggested that the introduction of a checklist improves aspects of teamwork that positively impact process outcomes. However, others suggest that for such improvements to be realised, the checklist as a tool requires support from system aspects to facilitate checklist use. Catchpole et al comment that future studies must investigate the required level and type of checklist compliance to achieve the observed clinical outcome effects.⁴⁸

5.8.9 Direct Observation of Checklist Use by Theatre Teams

This study demonstrates that direct observation studies capturing surgical checklists in use is a practical means to understanding what is happening in practice and whether the expected benefits are being realised. Direct observation provides real-time data capture. The observation approach in this study utilising multidisciplinary dual observers benefited the capture of this type of data. In addition, the study sample was varied across multiple NHS hospitals and across surgical specialties.

Direct observation of WHO SCC compliance is a common methodological approach as found in similar studies.^{201,288,300,301} In support of this methodological approach, Catchpole et al claim that direct observation is necessary when relating checklist use with compliance and outcome measures.⁴⁸ However, limitations are acknowledged with direct observation. The presence of observers may influence behaviours of the theatre team, yet in this study, the suboptimal findings indicate that observed performance was characteristic of natural behaviour. Real-time data collection may be problematic when managing data capture of specific points for lengthy periods of time, and data points may be missed. Observers were trained to compare

data at the end of each case to catch issues in data collection, resolving these through discussions to reach a consensus.

5.8.10 WHO SSC Compliance Audits

Compliance audits are in place for consistent and effective reporting. Compliance data should reflect if the checklist has been completed, although objective compliance has not been well defined to support this need.¹⁷² Reporting appears to merely reflect if the checklist has been attempted. There is neither a further quality breakdown to indicate satisfactory performance on any quality parameters nor clear indication of the checklist being complete in its entirety.

A multitude of factors have been highlighted as potential reasons for deficiencies in *expected* checklist use, although pinpointing an exact reason, or even a combination of reasons would likely be impossible due to the complexities of the situation and variance observed across the UK NHS hospitals. The literature is expanding, with findings in support of widespread WHO SSC compliance issues whilst audit data continues to report high compliance rates. Culatti et al found that compliance rates reported by administration audits ranged between 66% and 100%.²⁹⁸ This suggests that it may be time for the healthcare industry to address the audit process, the reporting of audit results, and to decide if audits are an appropriate and realistic way to measure actual WHO SSC use in practice.

5.9 Summary of Chapter

The WHO SSC continues to face resistance towards its use by healthcare professionals.³⁰² Therefore, evaluating its effect on patient care and outcome was considered essential for successful implementation.⁹¹ The WHO SSC demonstrated success with regard to clinical outcome improvements, gaining international popularity and global use. Yet, increasing evidence demonstrates issues of compliance, bringing into question whether the WHO SSC continues to hold the same clinical benefits if it is not being used as imagined.

The current debate appears to be whether to abandon the use of surgical safety checklists in surgery, i.e. if they are not performed as planned, do they benefit patient safety? Continuing to evaluate how they are being used will advance the decisions on what level of adherence is necessary for success and improved patient safety.

Regardless of this emerging evidence, the WHO SSC continues to be used in a mandatory capacity in the UK NHS, with audits remaining the primary means of measuring compliance. Local-level investigations could focus on recording the quality of checklist performance to strengthen the audit process, to identify adherence issues, and to support theatre teams in more effective WHO SSC implementation and use.

Chapter 6 Empirical Study II: Distributed Cognition in the Operating Theatre

6.1 Overview of the Chapter

In this chapter, Empirical Study II will be presented with the study aims and objectives. The methodological and analytical approach will be described, and the findings will be presented. The chapter will be concluded with a discussion and limitations and future work can be found in Chapter 7: Discussion and Conclusions.

6.2 Declaration

Validation of data: analysis of the raw data captured in this study was discussed with a senior scrub nurse. The senior scrub nurse was based at the hospital of St Cross, Rugby, UK and had consented to participate in the S3 Project.

The aim of this discussion was to validate the content and process steps of each item of the hip arthroscopy theatre preparation checklist as captured during observations and shadowing. Validation was a two-step process:

- 1. confirmation of the accuracy of the data captured;*
- 2. when discrepancies were identified, modifications were discussed in detail to ensure accurate capture of the process.*

6.3 Introduction

Empirical Study II investigates an existing cognitive artefact to understand how it is used to contribute to the preparation of the operating theatre within the wider joint cognitive system. The selected cognitive artefact in this study is an unofficial surgical checklist, referred to as the *hip arthroscopy theatre preparation checklist*.

The *hip arthroscopy theatre preparation checklist* is informal; it has neither been validated, nor is its use mandatory. It was initiated and developed by an orthopaedic consultant surgeon to ensure correct preparation of the operating theatre prior to the start of hip arthroscopy surgery. It is intended for use by the lead scrub nurse with the support of other personnel and artefacts.

A photograph of the original *hip arthroscopy theatre preparation checklist* can be found in *Appendix G – Hip Arthroscopy Theatre Preparation List*; this includes handwritten notes by the scrub nurse. In addition, the surgeon's name is covered to ensure anonymity. The *hip arthroscopy theatre preparation checklist* is the principal artefact in this study and will hereafter be referred to as the *preparation checklist*.

The *preparation checklist* is not exhaustive with regard to operating theatre preparation tasks but represents the surgeon's specific requirements and preferences which are considered relevant for an organised surgical flow. The need for the *preparation checklist* was focused on completion of key tasks prior to the patient's arrival into the operating theatre. The *preparation checklist* is intended to be led by the scrub nurse and includes key tasks which involve interactions with other theatre team members. In addition to interactions between the theatre team members, other artefacts (internal and external to the operating theatre) are required to support completion of the *preparation checklist* tasks. The *preparation checklist* is referenced in two main ways: it can be referred to via the form of a physical print-out in real-time or learnt and performed by memory recall. The *preparation checklist* does not

guide the style of interaction; the scrub nurse decides based on personal preference.

Many aspects of operating theatre preparation are related to the physical layout of equipment, accessibility to specific types of equipment, and correct equipment set-up. These aspects are all relevant to patient specific needs and the operating side (left or right). Other aspects of theatre preparation are related to surgeon specific needs, such as a required size of surgical gloves and the positioning of foot pedals related to their dominant side. The consultant orthopaedic surgeon responsible for designing the content of the *preparation checklist* informed me that it is intended to guide completion of these tasks prior to surgery and must be used in collaboration with rules, procedures, guidelines, and domain knowledge. Each task on the *preparation checklist* represents a task which is a shared goal to be completed by theatre team members, each with their part to play as an actor in the joint cognitive system. All actors utilise domain knowledge acquired through training and experience, artefacts, rules, and their implicit understanding to achieve shared goals.

This study investigates how the joint cognitive system is coordinated to prepare the operating theatre for surgery by utilising DCog as a guiding theoretical framework, and the methodological and analytical approach of DiCoT.²⁷⁷ This approach will identify the people interactions and artefact interactions required to prepare the operating theatre for surgery. These interactions will be framed in how information in the form of knowledge is distributed across the operating theatre environment, to ensure that each goal on the *preparation checklist* is achieved. The findings will highlight benefits and issues with the current distribution of knowledge, thus informing suggestions for redistribution of knowledge from the *preparation checklist* to other existing or new artefacts.

6.4 Research Question

The following research question was investigated:

RQ3: How do theatre teams use a surgical checklist to prepare the operating theatre for hip arthroscopy surgery?

6.5 Aims and Objectives

The primary aim of this study is to investigate how knowledge in the form of information is utilised and propagated by the theatre team members to understand how to prepare the operating theatre for hip arthroscopy surgery.

Therefore, this study investigates how a surgical checklist is used within the joint cognitive system to capture WAD. This is achieved by utilising DCog to investigate the distribution of knowledge between theatre team members by identifying their access to other individuals, and how they use the surgical checklist as a primary artefact to access information. This will describe interactions between individuals as actors within the joint cognitive system, and interactions between the primary artefact and other artefacts within the operating theatre.

Specific objectives to address the aim are:

- II-O-1: to describe the key interactions within the pathway of preparing the operating theatre for surgery using DCog as a guiding theoretical framework.
- II-O-2: to identify key information sources in the form of artefacts used by the theatre team members to prepare the operating theatre for hip arthroscopy surgery.
- II-O-3: to highlight knowledge distribution issues during preparation of the operating theatre for hip arthroscopy surgery.
- II-O-4: to suggest areas for the redistribution of knowledge to inform the design of future surgical checklists as cognitive artefacts.

6.6 A Brief Overview of Hip Arthroscopy Surgery

A brief overview of hip arthroscopy surgery is presented in *Box 2* below. This describes what hip arthroscopy surgery is, what medical conditions it is used to treat, and what is involved in the surgical procedure.

Box 2: A Brief Overview of Hip Arthroscopy³⁰³

What is hip arthroscopy?

Hip arthroscopy is a minimally invasive procedure that allows your surgeon to see inside your hip using a camera inserted through small cuts in the skin. It is used to examine, diagnose and treat problems that are causing pain and/or restricted movement in your hip.

What conditions are treated by hip arthroscopy?

A hip arthroscopy may be recommended if your hip pain hasn't responded to non-surgical treatments such as rest, physiotherapy, medications and injections.

Most commonly a hip arthroscopy is performed to:

- Remove small loose pieces of bone or cartilage inside your hip joint that can get caught between the bone surfaces and cause pain.
- Repair a torn labrum (the cartilage rim of the hip joint that helps provide a suction seal for the fluid in your joint). Sometimes the labrum can get torn and lead to episodes of acute pain in your hip and a feeling of giving way.

Hip arthroscopy may also be used to treat:

- Hip impingement syndrome, also called femora-acetabular impingement (FAI). A disorder where bone spurs cause damage around your socket or femoral head.
- Synovitis where the surrounding tissues of your hip joint become inflamed.
- Snapping hip syndrome where your tendon becomes damaged from repeated rubbing.
- Hip joint infection

What does hip arthroscopy involve?

A hip arthroscopy is often performed as a day case procedure under general anaesthetic. The operation takes between 30 and 90 minutes.

Your surgeon will make a small surgical cut to insert an arthroscope to look inside your hip. An arthroscope is made up of a tiny tube, a lens and a light source. Images are sent from the arthroscope to a video screen or an eyepiece, so your surgeon is able to see inside your joint.

The inside of your hip joint will be examined and your surgeon will decide whether an operation is required. Other small incisions may be made to insert medical instruments to remove fluid, diseased tissue or bone or to repair damage in your hip joint area.

Hip arthroscopy is a more recent type of elective orthopaedic surgery compared to other arthroscopic surgeries, such as knee arthroscopy and shoulder arthroscopy. All types of orthopaedic arthroscopy surgery require a vast amount of specialist technical equipment with which the theatre team members must be familiar, especially the scrub nurse. Specialist equipment such as a traction table, stack system, and C-arm X-ray machine are all required for hip arthroscopy surgery; photographs of those captured during the study can be found in *Appendix H – Hip Arthroscopy Specialist Equipment*.

The operating theatre is a complex and dynamic environment. Multiple theatre team members are present at any one time, with individual and cross-domain roles and responsibilities. In hip arthroscopy surgery, the lead consultant surgeon has ultimate responsibility for the patient and the surgical process, which is supported by the anaesthetic team, the nursing team including a scrub nurse and circulating nurses, and the radiology team. The scrub nurse is instrumental in the efficient running of a hip arthroscopy surgery. The team member performing this role must:

- organise the day's operating list of patients, coordinating with internal surgical team members and external hospital staff;
- know what equipment to set up in preparation for hip arthroscopy surgery;
- understand the roles of each theatre team member and how this relates to the role of the scrub nurse;
- understand the surgical procedure to support the surgeons with the correct piece of equipment at the right time within the surgical flow.

In order to prepare the operating theatre for hip arthroscopy surgery, a multitude of tasks must be completed prior to the operation commencing. Accurate preparation is also relevant prior to performance of the WHO SSC time-out section. This is to ensure that items on the WHO time-out can be successfully checked off before the operation commences. From the perspective of WAI, protocols, procedures, and guidelines are expected to fully

support this process. However, in practice WAD is far more complex and unstructured.

The core theatre team members required for hip arthroscopy surgery comprise of:

- a surgical team: consisting of a lead consultant orthopaedic surgeon and at least one supporting orthopaedic surgeon, typically a trainee;
- an anaesthetic team: consisting of a lead consultant anaesthesiologist and at least one supporting anaesthesiologist;
- a nursing team: consisting of one scrub nurse to assist the surgeons in the sterile field and a minimum of one circulating nurse in a support role, outside of the sterile field;
- a radiology team: consisting of one radiographer to operate the C-arm X-ray machine. On occasion, a trainee radiographer will also assist.

The vignette presented in *Box 3* below introduces the complexities of preparing the operating theatre for hip arthroscopy surgery and how preparation can impact the surgical flow. The vignette was produced from my observations captured while shadowing the scrub nurse. The content is a narrative which summarises preparation tasks at the beginning of the day and the transition into the first surgery; key tasks, direct observations, and comments from the scrub nurse are presented.

Box 3: Operating Theatre Preparation for Hip Arthroscopy

It's 7am, the scrub nurse is already in the operating theatre. The anaesthetist is on the ward attending to the 1st patient. The consultant surgeon is elsewhere, either with the anaesthetist, reading patient notes, or attending the morning briefing. Other circulating nurses are running in and out of the operating theatre supporting the scrub nurse to gather equipment and complete essential tasks.

Preparing the operating theatre for surgery is driven by the experience of the scrub nurse and supported by other theatre team members. In no particular order, the scrub nurse requires awareness of the following: preparation for the lead surgeon with respect to the theatre preparation list, identifying how many circulating nurses are available and whether this is enough to support the days tasks, checking if the radiographer is going to be on-time, checking the availability and access to specialist equipment a) was it ordered and b) is it available. The workload during this period is high for the scrub nurse moving from one from one task to another with multiple interactions.

One round of preparation is completed with the scrub nurse in her surgical blues, at this point she is unsterilised and able to freely move around the operating theatre. Another round of preparation requires the scrub nurse to be sterilised and stationed in the sterile area. Once sterilised, the scrub nurse begins by arranging the equipment trolleys around the sterile area and organising equipment trays. In addition, input of the patient information, video monitoring set-up, and multiple cables must be connected and organised on the mayo stand. During these tasks, the scrub nurse is reliant on support from the circulating nurse who is positioned outside of the sterile field.

During completion of preparation tasks, the patient is rolled into the operating theatre from the anaesthetic room, which is an adjacent room. Behind the scrub nurse the patient is transferred to the traction table in either the supine or lateral position, and sterile draping of the patient commences. Multiple tasks are being performed concurrently by multiple individuals and the conversations increase with more people in the operating theatre.

The scrub nurse is busy with final preparation, it's just before 8am and the consultant surgeon arrives into the operating theatre.

A short time later, the WHO SSC time out section is completed and the first operating case commences. As the surgeon slides the scope inside the open wound of the patient's hip, there is no picture on the surgeon's video monitor. The scrub nurse confirms everything is plugged in and the scope is attached to the video monitoring machine but realises it was not calibrated during preparation. A short delay occurs and the operation continues. The surgeon searches for the pedals on the ground with his foot (these are hidden underneath the table drapes), the pedal is out of reach and the circulating nurse has stepped out of the operating theatre unannounced. The anaesthetist leaves his station to assist in re-positioning the pedals as everyone else in the sterile area is sterilised and cannot physically move the pedals. The operation continues and the surgeon requests the shaver, the scrub nurse searches for the shaver on the mayo table but it is missing. There is a frantic moment of searching and the scrub nurse realises it is not available. The anaesthetist voices his concern about how much longer the patient will be under anaesthetic, the surgeon comments on the frequent delays to the busy day ahead. The scrub nurse requests another shaver, but the circulating nurse has no idea how to find one because she is new. The scrub nurse is stuck within the sterile field and verbally instructs the circulating nurse. A new shaver is opened, connected and the operation continues.

6.7 Study Scope

In a complex and dynamic operating theatre environment, it is impractical to attempt to observe every aspect of lengthy surgeries across different specialties. Therefore, a specific surgery was selected for this study. In addition, each surgery has multiple phases, again producing a vast amount of data. Therefore, one phase was defined for the study scope to focus the investigation and maximise the quality of the data.

During the S3 Project observations, detailed in *Chapter 5: Empirical Study I*, many elective orthopaedic surgeries were observed, including hip arthroscopy surgery. Hip arthroscopies were selected for this empirical study as they are relatively short in duration compared to arthroplasty surgery i.e. hip replacements. It is also one of the newest orthopaedic surgeries; therefore, from a process development standpoint, there is opportunity for advanced understanding.

In addition, to further focus the research scope, a period of activity was specified. The selected period is preparation of the operating theatre, commencing with the arrival of the scrub nurse into the operating theatre and ending prior to initiation of the WHO SSC time-out section. This was determined to be relevant for the following reasons:

1. during *Empirical Study I (Chapter 5: Empirical Study I)*, process deviations captured as ‘glitches’³⁰⁴ within the surgical process were identified by the research team to be associated with preparation tasks that had been forgotten, missed, or skipped. For example, specialist equipment not ordered or checked as available in the operating theatre prior to the start of the surgical procedure can have detrimental impacts on the surgical process flow, and in extreme cases, may result in termination of the surgery;
2. correct preparation of the operating theatre is key to successfully checking off items on the WHO SSC time-out. The operation can only commence once preparation and the WHO SSC time-out has been completed.

It was evident from previous observations that the preparation phase was a key element to an overall smooth process flow and resembled the preparation phase of other high-risk industries, such as in aviation prior to aircraft taxiing. The period prior to the WHO SSC time-out section will hereafter be referred to as the preparation phase.

To confirm this approach to the study scope, this was further discussed with hip arthroscopy surgical team members, including: a lead consultant orthopaedic surgeon, two trainee orthopaedic surgeons, and five orthopaedic scrub nurses. The aim of these informal and unstructured discussions was to elicit individual opinions on the importance of preparing for hip arthroscopy surgery, and in their experience how this impacts the overall surgical process flow. Therefore, it was concluded from previous observations and discussions that the preparation phase was pertinent for a focused research scope.

In addition, the role of the scrub nurse during the preparation phase was determined to be extremely significant in managing multiple tasks in the operating theatre environment, as they are responsible for leading the *preparation checklist* prior to performance of the WHO SSC time-out section. Therefore, considering the overarching joint cognitive system whereby all actors, artefacts, and tools have a role to play, the scrub nurse is considered central to these interactions. The defined research scope is aimed to provide novel insight into WAD during preparation of hip arthroscopy surgery.

6.8 Application of Distributed Cognition and Distributed Cognition for Teamwork

The application of DCoG as the guiding theoretical framework and DiCoT for the methodological and analytical approach is discussed in detail in *Chapter 4: Research Process*. This study investigates the operating theatre as a joint cognitive system and adopts the DiCoT methodology to support identification of key aspects in the operating theatre environment. The following themes have been applied:

1. Theme A Physical model: to capture the layout of the operating theatre environment;
2. Theme B Physical model: to capture the layout of the sterile area within the operating environment;
3. Theme C Information flow: to capture how information flows between actors within the operating theatre environment; and
4. Theme D Artefact flow: to capture artefacts utilised by the actors, and how they facilitate the transfer of knowledge within the operating theatre environment.

These themes support the identification of an area of focus i.e. the preparation phase, and will utilise the DiCoT methodology to capture and analyse:

- the layout of the operating room;
- the information flow between the scrub nurse as the focal actor and other actors; and
- how the preparation checklist is used in the joint cognitive system, i.e. in conjunction with other people, existing artefacts, and tools.

The findings will identify issues within the existing environment. This study neither intends to identify user requirements nor define guidelines. It will utilise the DiCoT methodology to identify opportunities for the redistribution of knowledge from an existing artefact to other and new artefacts. In addition, it is aimed to support the design of future surgical checklists, and additional redesign factors may be proposed to support the overall process flow in the operating theatre environment.

6.9 Methods

6.9.1 Study Setting

The study was conducted in one UK NHS hospital. The hospital was selected as it was already participating in the S3 Project (referred to in *Chapter 5: Empirical Study I*). The ethics approval can be found in *Appendix E – S3*

Project Ethics Approval. In addition, this hospital was identified as performing a high frequency of hip arthroscopy surgeries.

Access to the operating theatre was previously granted under the S3 Project via an observer passport. On each observation day, I obtained verbal approval from the theatre team members prior to observations to ensure that my presence in the operating theatre was accepted.

Hip arthroscopy surgeries were typically performed in the same operating theatre, theatre 1; therefore, the layout of the room remained consistent. The members of the theatre team remained relatively consistent for all observed cases observed; however, the role of scrub nurse was rotated between five different trained nurses. The lead consultant orthopaedic surgeon remained the same; however, trainee assisting orthopaedic surgeons rotated and varied in their experience level. All supporting theatre team members varied in their roles depending on availability of trained staff. On occasion, external personnel were present in the operating theatre, such as equipment supplier company representatives or trainee nursing staff. External personnel were not considered as part of the core theatre team, and therefore, were excluded from data collection. However, discussions with the equipment supplier company representative were considered beneficial to advancing understanding of the equipment used, and these discussions were referenced below in 6.9.2. *Study Design.*

6.9.2 Study Design

The study design utilised an exploratory and holistic approach; methods were not systematically conducted. A combined and iterative approach was adopted to maximise the quality of data collection via real-time opportunities. The methodological approach in this study followed the DiCoT methodology²⁷⁷ to guide data collection. The qualitative approach generated a vast amount of data, this was considered necessary to cover aspects of the operating theatre preparation that observations alone may not have captured. The analytical approach required structure from qualitative data guidelines^{305,306} to populate

the themes proposed in the DiCoT framework. Analysis of the findings utilised both the DCog and DiCoT frameworks and were supported by the quality of qualitative data guidelines proposed by Pope.³⁰⁷ In addition, aspects of triangulation were utilised to facilitate validation of data from multiple sources.³⁰⁸

Figure 6-1: Methods Process Flow below illustrates the methods process flow, which includes:

- Phase I – Phase IV: these phases illustrate the methods used to collect the study data;
- Phase V and Phase VI: these phases illustrate analysis of the study data.

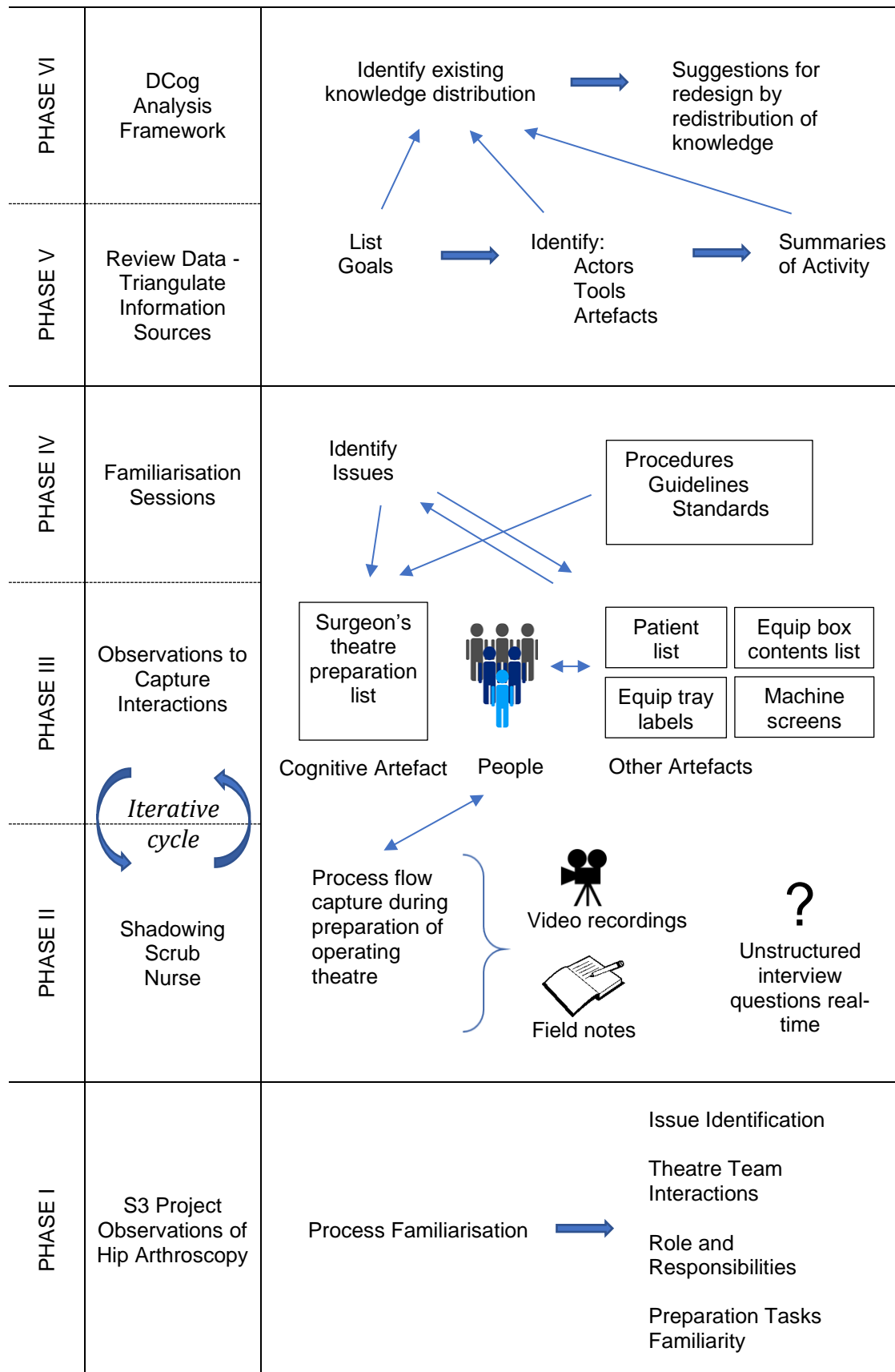


Figure 6-1: Methods Process Flow

6.9.2.1 Who

I was the researcher in this study. This approach was justified as single researcher observations are typical in DCog studies.^{277,278,309}

6.9.2.2 Observer training

Throughout my professional experience, I have observed people at work, and I have extensive experience collecting and analysing data related to WAD in practice. However, specialist training and experience was gained in observing theatre teams from the S3 Project training and observations; see *Chapter 5: Empirical Study I*. If any difficulties were presented with understanding technical aspects that may impact the process flow and thus data collection, I discussed these with the lead consultant orthopaedic surgeon or the scrub nurse for clarification.

6.9.2.3 When

The period of data collection was January 2012 to September 2012. The period of data collection overlapped with the S3 Project (see details in *Chapter 5: Empirical Study I*) data collection period; therefore, data collection in this study was organised around the S3 Project data collection schedule.

6.9.2.4 How

Observations:

The need for an extensive phase of familiarisation with hip arthroscopy surgery was not required due to my previous observation experience on the S3 Project, detailed in *Chapter 5: Empirical Study I*. Exposure to hip arthroscopy surgery during S3 Project observation provided a foundation of experience and understanding of the process flow. However, the focus of my observations shifted from the complete surgical process in the S3 Project observations to preparation of the operating theatre for hip arthroscopy surgery.

A total of twenty hip arthroscopy operations were observed in total. I was present in the operating theatre from the start of preparation to the end of each operation. The primary focus was the preparation phase; however, from experience, I recognised the importance of observing the full process flow and the connections between each operation, as some issues can stem from previously conducted operations.

Observations were concluded when data saturation was achieved, and no additional information could be gained by further observations.

6.9.2.5 Shadowing of scrub nurses for process walkthroughs

This research was focused on preparation of the operating theatre for hip arthroscopy surgery. Therefore, I shadowed individual scrub nurses from arrival in the operating theatre to conduct process walkthroughs within this pathway of activity. To ensure the productivity of these sessions, I shadowed the scrub nurses assigned to each observed operation. This supported the person-oriented approach as proposed by Suchman and Trigg for focused data collection.³¹⁰ In addition, this supports the role of the scrub nurse as a key actor within the preparation phase. I shadowed a total of five different scrub nurses during the twenty observed hip arthroscopy surgeries.

The aim of the shadowing sessions was to understand how the scrub nurse used the *preparation checklist* to complete all preparation tasks, i.e. to identify the process flow, communications, and interactions with other theatre team members and with other artefacts. Preparation tasks were recorded via freehand notes, and when required, a handheld video recorder was used. During these sessions, specific attention was given to the recording of interactions between the scrub nurse and other theatre team members, preparation tasks, and interactions with artefacts within the operating theatre environment.

The method of shadowing was agreed in advance with each scrub nurse. Every effort was made not to intervene with the smooth running of their tasks.

The main restriction was proximity to the scrub nurse when sterilised and in the sterile area. To ensure that sterility within the sterile area was maintained, I positioned myself in the non-sterile area in as close proximity to the scrub nurse as possible. This limited the physical distance of interaction but did not hinder the process walkthroughs or the quality of the data collected.

6.9.2.6 Note taking (freehand)

Following an ethnographical methodological approach, freehand notes were taken real-time during observations. I was familiar with the overall process of hip arthroscopy; therefore, it was decided not to directly follow the hip arthroscopy process booklet²⁸⁰ as previously used in the S3 Project.

Handwritten notes were considered the most appropriate method to capture important processes, issues, and contextual scenarios. These were recorded in an A4 notebook.

6.9.2.7 Unstructured interviews

During observation sessions, opportunities presented themselves to further explore why some tasks were completed in a certain way. I took opportunities to elicit more detailed information from the necessary theatre team members by asking unstructured questions relevant to the context observed. Consideration was given to the theatre team members to always ensure minimal interruption to their tasks and the surgical process flow. The aim of these unstructured questions was to ensure appropriate interpretation of context and advancement of my understanding of what was being observed to improve the quality of data collection.

6.9.2.8 Narrative data

Comments by theatre team members were captured as narrative data in the form of handwritten notes. When necessary, context information accompanied narrative data. No information related to the identification of individuals was captured, only their role in the operating theatre.

6.9.2.9 Video recordings

The operating theatre is an extremely complex and dynamic environment; therefore, video footage was captured during five observation sessions. This data was used as a memory aid for post-observation review when it was necessary to confirm the observed interactions during preparation of the operating theatre for hip arthroscopy surgery. Agreement to use a video recorder was obtained by the lead consultant orthopaedic surgeon and the relevant theatre team member. There was no requirement to capture identifying features of individuals.

6.9.2.10 Access to technical reference material

I referred to technical reference materials for familiarisation of surgical equipment when required. This material is the same as those available to theatre team members; it mostly details the technical aspects of the equipment and how they are used in surgical procedures. Review of these materials was for reference purposes only, to advance my understanding of the equipment used in the operating theatre and how the equipment relates to the preparation tasks. No further analysis was conducted on this technical material.

6.9.2.11 Discussions with equipment company representatives

On rare occasions, equipment company representatives were present in the operating theatre to support theatre teams in the use of their supplier's surgical equipment. This was not directly related to the study scope but was added as insightful knowledge, which further supported understanding of how theatre team members interacted with surgical equipment and if this related to preparation tasks. This also presented another opportunity to understand the context of how theatre teams are trained. Any issues with the equipment were discussed real-time and the company representative either assisted in on the spot training of how to use the equipment, or if the issue was something that could not be fixed real-time, made a note to take this issue back to the company office.

6.9.2.12 Scrub nurse familiarisation sessions

Mid-data collection, I designed a hip arthroscopy familiarisation session in collaboration with trainee orthopaedic surgeons. These hip arthroscopy familiarisation sessions were conducted with three trainee scrub nurses. They were shown how to prepare surgical equipment for hip arthroscopy surgery. The familiarisation sessions were led by trainee orthopaedic surgeons whilst I observed. These sessions were incorporated into the methodological approach for a dual purpose:

1. to build familiarity with the hip arthroscopy procedure to ensure the quality of observations; and
2. to identify any areas or specific issues that may have been key focus points during the remaining observation sessions.

Authorisation was granted by the hospital theatre manager and the lead consultant surgeon to conduct these sessions with three of the junior scrub nurses. Approval was based on there being no negative impact on any formal training the junior scrub nurses may receive in the future as these were familiarisation sessions only.

All operating theatres were occupied in the hospital with busy theatre lists from 7am to 7pm. Therefore, an operating theatre scene was set up as a mock environment in a separate room which was assigned by the theatre manager. Some environmental factors could not be replicated in this setting and were considered unnecessary, such as sounds, other team members etc. A trainee orthopaedic surgeon acted as a lead consultant surgeon. On occasion another trainee orthopaedic surgeon was present and acted as an assisting trainee surgeon. During these sessions, a hip model was utilised; this model had moving parts to represent the primary parts of a real hip. A photograph of the hip model used in these sessions can be found in *Appendix I – Hip Model*. The model was draped to represent a realistic scenario. Due to ethical clearance restrictions, the use of a cadaver (deceased body part) was not possible, neither was this required for familiarisation sessions. The hip model was placed on a regular office table as a traction table was not necessary. Standard

equipment trays were used during the sessions. The C-arm X-ray machine was not necessary for these sessions.

Basic material was produced for reference of patient anatomy and the hip arthroscopy procedural steps, including details of associated equipment. This material was produced for familiarisation purposes and not validated. I created the material based on observation data, shadowing sessions, and review of surgical equipment reference material. Two trainee orthopaedic surgeons reviewed this material for accuracy; additionally, it was marked with a caution '*for familiarisation and illustration purposes only.*'

Familiarisation sessions consisted of each of the three trainee scrub nurses being available for a two-hour time slot. During the sessions, procedural steps were demonstrated by the trainee orthopaedic surgeon. Safety of handling equipment was ensured; all equipment was disconnected to ensure that the user was safe. During these sessions, time was allocated throughout for questions and answers. I noted aspects which may have impacted preparation of the operating theatre, such as questions, areas of confusion, equipment terminology issues, and missed process steps during equipment set-up.

6.9.3 Research Ethics

As previously discussed, ethics approval was covered by the S3 Project. Participants who previously consented to being observed in *Empirical Study I* were selected to participate in this study. Any deviations from the original S3 Project methodology were verbally disclosed to the participants, i.e. in this study only one observer was present in the operating theatre as opposed to two previously. In addition, it was possible that theatre team members would be asked questions in order to clarify my understanding of activities, although extreme care was taken not to impact theatre team members' tasks and process flow. Prior to each surgical case observed, all participants were asked if they still consented to being observed and if they required any clarification on the intent of the study and my role as a researcher.

I had no interaction with the patients. Patient related data was observed but all patients were under anaesthetic when entering the operating theatre. Therefore, patient consent was not required by the ethics committee. All data was de-identified to ensure patient anonymity.

Data was stored on university password protected computers.

6.10 Results

The findings are presented in the format of DiCoT themes A-D below.^{277,278} Observation data produced sufficient findings for themes A and B; populating the content of themes A and B required a phased approach:

Phase 1: in phase 1, sketches were produced of the operating theatre room layout and station view. The content of these sketches was evolved in an iterative approach during multiple observation sessions. During observation sessions, quiet periods were utilised to populate the content of the final diagram.

Phase 2: in phase 2, details of the environment were refined to populate the summary tables associated with the operating theatre room layout and station view diagrams.

Triangulation of the raw data from several sources and data coding of observation notes were required for themes C and D. All other data points were used to:

- a) expand on knowledge
- b) confirm steps
- c) validate summary descriptions.

To build on the DiCoT methodological and analytical approach, a tabular description was added to analyse data related to theme C: information flow, and theme D: artefact flow. The tabular description data was validated by a senior scrub nurse. The senior scrub nurse highlighted aspects of the process

that had been updated or deviated since the data collection period and these are recorded for information purposes, although no further analysis has been performed.

Table 6-1: Summary Description of the Environmental Context below provides a summary description of the environmental context of the operating theatre.

Table 6-1: Summary Description of the Environmental Context

Environmental Context	
Environment: Operating theatre	<p>The operating theatre was consistent for the duration of the study as all observations were conducted in the same operating theatre. Therefore, aspects related to the physical layout of the environment were stable, and the findings did not differ due to environmental context.</p> <p>Non-sterile and sterile fields were not physically marked on the floor.</p>
Environment: Access to theatre	<p>External access to the theatres department is controlled via a locked external door which requires a badge or access via the theatre receptionist.</p> <p>Internal access to operating theatres is via the theatre door, which is unlocked. Anyone can access the operating theatres once inside the theatres department.</p>
Environment: Temperature	<p>The operating theatre was kept at a cool temperature as per NICE Guidelines.³¹¹</p>

Table 6 1: Summary Description of the Environmental Context – Continued

Environmental Context	
Time	<p>The time of day for conducting the preparation checklist varied due to unpredictable durations of each hip arthroscopy operation. Goals to be completed on the preparation checklist would ideally be completed prior to the patient's arrival in the operating theatre. However, the preparation phase and the patient's arrival in the operating theatre was found to cross-over; on several occasions this created competing demands.</p> <p>Some goals were unique to the start of the day compared to throughout the day. For example, setting of lights at the start of the day required an extra step of turning the main theatre lights on, setting the temperature, and checking that specialist equipment was available. Therefore, additional goals were observed and recorded as unique to the start of the day, whereas other goals were common throughout the day and performed prior to each operation.</p> <p>Regarding theatre preparation time, no explicit reference was recorded. However, observations found that this phase was time pressured due to high turnover of scheduled operations.</p> <p>Surgical complications were not observed.</p>
Personnel	<p>The number of theatre team members varied. The consistent minimum core team included: one lead consultant orthopaedic surgeon, one lead scrub nurse, one lead anaesthetist, one circulating nurse, and one radiographer. Additional theatre team members included: at least one trainee orthopaedic surgeon, occasionally a trainee scrub nurse, one or more anaesthetic assistants, one or more additional scrub nurses, and surgical trainees.</p>

Table 6 1: Summary Description of the Environmental Context – Continued

Environmental Context	
Clothing	<p>Operating theatre clothing was worn by all theatre team members. The only observed difference was the operating theatre shoes (white operating theatre boots for the lead consultant orthopaedic surgeon and blue operating theatre shoes for all other theatre team members).</p> <p>Note: In hip arthroscopy surgery, an X-ray protection vest must be worn under the sterile gown to protect theatre team members from harmful radio waves from the X-ray machine.</p>

6.10.1 Theme A: Physical Model of the Operating Room Environment

Theme A provides a pictorial representation of the physical model of the operating environment in *Figure 6-2: Physical Model - Room Level View - Operating Theatre Layout* below; this illustrates the room level view of Operating Theatre #1 with key stations and key personnel represented. An associated summary is provided in *Table 6-2: Summary of Room Level View* below, which describes the interactions between the people via access to actors. Specific notes and issues are also highlighted in the table.

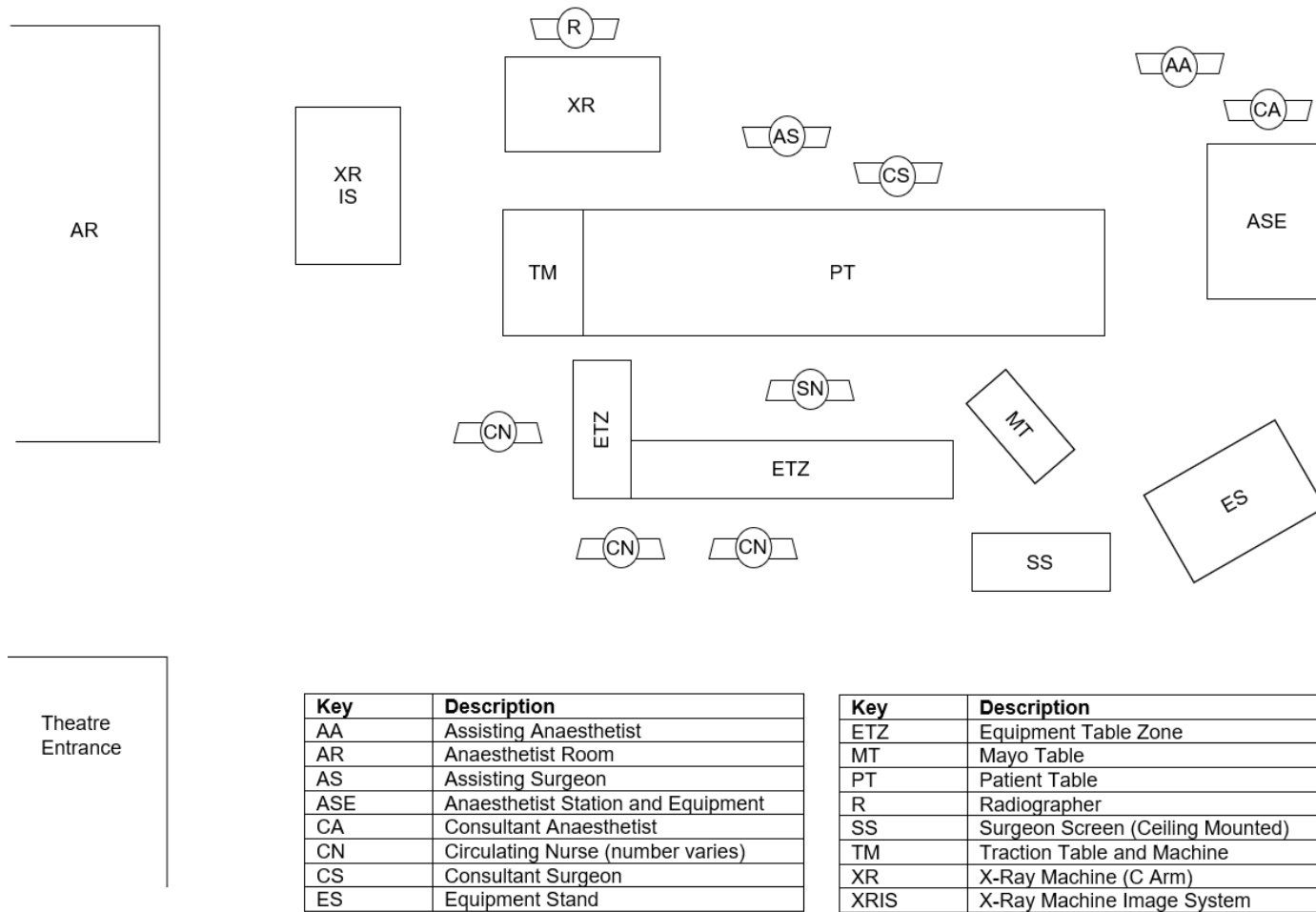


Figure 6-2: Physical Model - Room Level View - Operating Theatre Layout

Table 6-2: Summary of Room Level View

<p>Summary</p> <p>The operating theatre is the main hub of activity for preparation tasks when preparing for hip arthroscopy surgery. Access to the operating theatre is obtained via two doors: the main operating theatre door and the induction room door, which is an adjacent room to the operating theatre.</p> <p>Actors have specific roles and duties within the operating theatre. During preparation tasks, they are free to move within all areas of the operating theatre up to the point that the sterile field is active. At this time, restrictions are imposed for sterile and non-sterile theatre team members to avoid contamination within the sterile area. Additional preparation tasks are required at this time.</p> <p>Awareness of the sterile field being active is only known via physical changes to the operating room environment with regard to equipment layout and the relevant team members being scrubbed and in their respective sterile zone workstation.</p>
<p>Details</p> <p><u>Communication (Access to Actors)</u></p> <p>The main form of communication between theatre team members is verbal. Within the operating theatre, verbal interactions occur by calling across to each other within the operating theatre.</p> <p>During preparation of the operating theatre, the patient is being prepared in the induction room. These tasks segregate members of the theatre team by their roles and responsibilities, thereby also restricting verbal communication between team members. If communication is necessary, then the door to the induction room must be open for verbal communication to be heard.</p> <p>When the patient arrives into the operating theatre, all theatre team members are present in the main operating theatre. Therefore, verbal communication is not restricted by walls, doors etc. When verbal communication is not heard, voices are raised to gain the attention of the required team member.</p> <p>Communication with external actors is typically via email or telephone.</p>

Table 6 2: Summary of Room Level View - Continued

<p><u>Access to Artefacts</u></p> <p>Artefacts at room level are either shared or accessible only by specific theatre team member roles.</p> <p>Shared artefacts are always visible and accessible to all theatre team members. They include:</p> <ul style="list-style-type: none"> - a white board on the operating theatre wall; - the patient list either displayed on a monitor or a printed paper copy which is pinned to a white board on the operating theatre wall. <p>Some artefacts are only accessible by specific roles, including:</p> <ul style="list-style-type: none"> - solution bottle labels - an equipment tray contents list.
<p>Notes • Any notable aspects of the environment</p> <p>Upon entering the main operating theatre door, the sterilisation area is located directly within this area. This can impact access to the operating theatre and free movement during times when theatre team members are performing sterilisation tasks. No signage is available to inform external actors that this task is being performed.</p> <p>Once inside the operating theatre, the area of the room is relatively large compared to other operating theatres, which enables unrestricted movement in the non-sterile field.</p>
<p>Issues • Any aspects impacting workload and performance</p> <p>Access to knowledge is restricted by the geographical separation between the induction room and the operating theatre, which creates a physical barrier and segregates theatre team members. This barrier within the joint cognitive system results in blocked visible and verbal communication via a door.</p>

Table 6 2: Summary of Room Level View - Continued

The WHO SSC sign-in section is conducted in the induction room, which segregates the theatre team members. Announcement that the patient is ready for theatre is often only known when the induction room door is opened, and the patient is wheeled into the operating theatre. This has potential to impose a workload impact as the time available for preparation is typically unknown.

Performance factor: the operating theatre entrance is an unlocked door which facilitates open access for external actors. The process flow is frequently disrupted by external actors accessing theatres and verbally communicating questions. This distracted the theatre team members and disrupted the surgical flow.

6.10.2 Theme B: Physical Model of the Operating Theatre at Station Level

Theme B provides a pictorial representation of the physical model of the operating environment at station level in *Figure 6-3: Physical Model - Station Level View - Operating Theatre Sterile Field Layout* below; this illustrates the station level view of operating theatre #1 with specific focus on the sterile field, with key stations and key personnel represented in relation to the scrub nurse's primary workstation and associated equipment set-up. The bordering unsterile area is also highlighted. An associated summary is provided in *Table 6-3: Summary of Station Level View* below, which describes the interactions between the individuals via access to actors; specific notes and issues are also highlighted in the table.

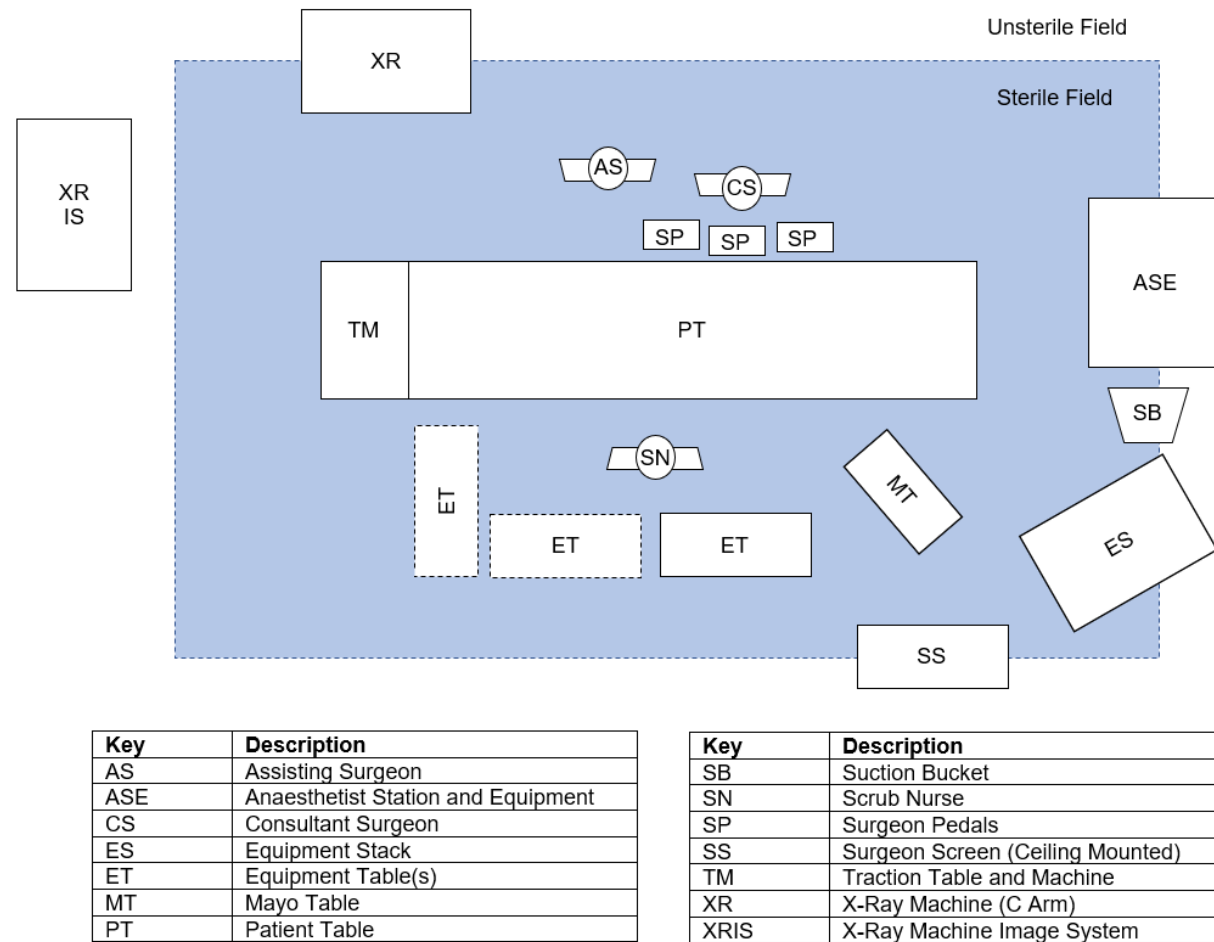


Figure 6-3: Physical Model - Station Level View - Operating Theatre Sterile Field Layout

Table 6-3: Summary of Station Level View

<p>Summary</p> <p>During preparation of the operating theatre, there are two sub-phases: one when the sterile field is inactive and one when the sterile field is active.</p> <p>This is a significant transition point in the distribution of knowledge between theatre team members. Awareness of this transition is important as it determines which theatre team members are allowed in the sterile field to ensure decontamination of equipment.</p> <p>This knowledge is shared by a non-verbal indication when equipment is moved within the operating theatre and the scrub nurse is sterilised. During preparation tasks, control of the sterile field appears to be the responsibility of the scrub nurse. It is critical that the sterile field remains sterile to open sterilised surgical equipment and to ensure decontamination.</p> <p>The scrub nurse has restricted movement at this point of preparation and is reliant on other theatre team members such as the circulating nurses.</p> <p>Most of the sterile surgical equipment surrounds the scrub nurse workstation. Multiple equipment trolleys surround the scrub nurse workstation; often there is an extensive number of equipment trays, and the scrub nurse is responsible for organising these to ensure that they are all accessible from within the sterile field at the workstation. In addition, there is an extensive number of machine cables, tubes etc., which all require organisation in and around the sterile field. This hinders movement around these items due to risk of contamination.</p>
<p>Details</p> <p><u>Communication (Access to Actors)</u></p> <p>When the scrub nurse is in the sterile field, this impacts interactions with other theatre team members; verbal communication becomes dominant and physical contact is restricted.</p>

Table 6 3: Summary of Station Level View – Continued

<p>Verbal communication can be further restricted by the scrub nurse wearing a surgical mask. This is required when opening equipment trays and handling sterile surgical equipment. The volume of verbal communication transfer is critical to ensure that communication is clear and heard accurately. Low voices often require repetition due to unheard or misheard communication. The scrub nurse typically raises their voice during these preparation tasks.</p> <p>Other theatre team members located external to the sterile field, in the unsterile area may not be heard due to a physical barrier from the equipment trolleys, which increases the physical distance between actors.</p> <p><u>Access to Artefacts</u></p> <p>The scrub nurse cannot physically touch any artefacts that are not sterilised due to risk of contamination.</p> <p>The scrub nurse workstation is situated around the centre of the operating theatre. Therefore, shared artefacts may not be visible from this station as the physical distance has increased from the operating theatre walls. Any information from these artefacts must be verbally communicated via a circulating nurse.</p>
<p>Notes • Any notable aspects of the environment</p> <p>The scrub nurse is in a confined area surrounded by equipment.</p> <p>Physical access to anything outside of the sterile area relies on external team members to access and communicate.</p>
<p>Issues • Any aspects impacting workload and performance</p> <p>Drapes are placed over the patient, over the C-arm X-ray machine, over cables, and other equipment which is in close proximity to the sterile field to ensure sterilisation. Drapes hinder visibility and access to covered items.</p> <p>Extensive cables, tubes etc. create added workload to arrange on the mayo stand.</p>

Table 6 3: Summary of Station Level View – Continued

The scrub nurse must wear an X-ray vest underneath the sterile gown. When this step is missed, it has an impact on preparation tasks as they must be paused, which results in a delay to the surgical flow. If the operation has commenced, any theatre team member not wearing an X-ray vest must stand behind a protective shield; this has a performance impact for theatre team members within the sterile field.

6.10.3 Theme C: Information Flow

Theme C provides a pictorial representation of the information flow in *Figure 6-4: Information Flow Between Central Actor and Other Actors* below; this illustrates a representation of the communication flow with the scrub nurse as the central actor and the interactions with other theatre team members as actors within the operating theatre. An in-depth analysis of the findings is arranged as tabular descriptions which can be found in *Appendix J – Preparation Checklist Items*; these detail the interactions between actors.

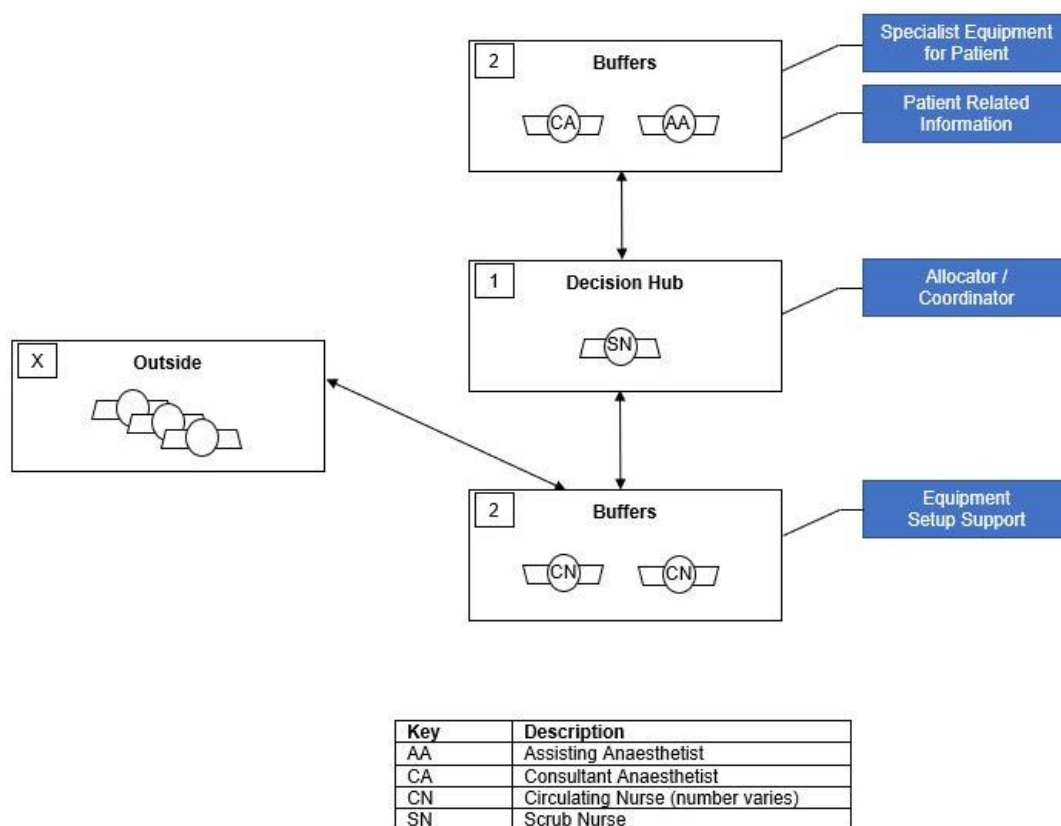


Figure 6-4: Information Flow Between Central Actor and Other Actors

6.10.3.1 Summary of information flow findings

The findings are provided as a description of key interactions in the flow of information. Detailed communication analysis was not performed in this study. The findings identified that the scrub nurse acts as the decision hub supported by buffers. A formal role as a filter was not identified.

Information in the form of knowledge is distributed in an apparent non-structured way around the operating theatre. All tasks visibly appear to be completed; however, in-depth analysis of the quality of task completion highlights that steps can be performed incorrectly or missed, which has an impact on the surgical flow.

The findings for information flow can be organised into the following categories:

1. Leadership and management: the scrub nurse assumes the role of the leader during theatre preparation tasks. Management of preparation tasks is mostly implicit as findings suggest that performance of goals is known from familiarisation with the theatre team members, familiarisation with the preparation process for hip arthroscopy surgery, and domain specific experience.
2. Communication and coordination: in the distribution of knowledge for shared goals, there was a lack of visibility and structure for theatre team members. Implicit knowledge is favoured over explicit knowledge sharing from the initiation of a goal, through performance of a goal, to completion of a goal. No reference to tacit knowledge of how to complete the goals was identified. During preparation of the operating theatre, competing demands continually divided attention in the form of interruptions and distractions. Often concurrent tasks were performed during the preparation phase.
3. Teamwork and decision-making: throughout the observations, all core theatre team members were consistent, which resulted in familiarity within the group of actors. No new actors were present during preparation tasks in the operating theatre. This level of familiarity was found to facilitate distribution of knowledge as each actor displayed an implicit understanding of their role and responsibilities within the joint cognitive system. External actors assigned to the operating theatre differed; this impacted availability and timing issues but did not impact preparation tasks.

6.10.4 Theme D: Artefact Flow

Theme D provides a description of the artefact flow within the operating theatre environment. This illustrates how the principal artefact, *the preparation checklist*, is used via interactions with other mediating artefacts within the operating theatre.

6.10.4.1 Principal artefact: preparation checklist

The findings describe how the *preparation checklist* is used in the preparation of the operating theatre for hip arthroscopy surgery. *Box 4* below presents the original items as copied text and excludes the handwritten notes and surgeon's name.

Box 4: Hip Arthroscopy Theatre Preparation Checklist

[Surgeon's name] Hip Arthroscopy Theatre Preparation

- Sets and soft pack ready
- Spinal table into theatre
- Traction, see traction set up
- Stack – plugged in correctly
 - Add and save patients for list
 - Set screens in right place for operation
 - Enter all details on surgeon's screen, in right place
 - Foot pedals in right place
- Lights in correct place
- Surgeons screen in correct place (right or left)
- Saline 3 bags plenty, prepared in bucket of warm water
- Drip stand with bells ready
- Suction unit, plenty of liners ready
- Large bucket under table for suction tubing
- X-ray machine in ready on correct side, called radiographer
- Check printer and paper ready
- Xylocaine 1% with adrenaline 1:200,000
- Marcain 0.5%
- Surgipads + Mefix if required
- Biogel 8.5 gloves
- Pink chlorhexidine prep
- Arthrocare machine

6.10.4.2 Mediating artefacts

In the artefact flow, interactions between the principal artefact and other artefacts within the operating theatre are referred to as *mediating artefacts*.

The mediating artefacts are detailed in *Table 6-4: Mediating Artefacts* below with a short description of their representational state. During observations, photographs were taken of these mediating artefacts, which can be found in *Appendix K – Operating Theatre Artefacts*.

Table 6-4: Mediating Artefacts

Artefact Name	Representational State Description
Patient list	Computer monitor Paper print out (A4 white paper)
Display board	White board on operating theatre wall with marker pen
Device monitors	Display screens
Equipment box labels	Sticky labels on equipment boxes: handwritten or printed
Equipment tray labels	Printed and attached to outside of equipment tray or handwritten on the equipment tray cover
Solution labels	Sticky labels on solution bottles / bags to identify contents: printed
Schedules	Paper print out
Equipment order form	Electronic on computer screen Paper print out

6.10.4.3 Summary of artefact flow findings

An in-depth analysis of the findings is arranged as tabular descriptions, which can be found in *Appendix J – Preparation Checklist Items*. One tabular description is provided for each goal; all eighteen goals are described with their associated information within the DCog framework describing the interactions between the actors and the interactions with artefacts. This information is provided as a narrative and describes how knowledge is distributed within and between actors. In addition, the artefacts are described with their representational state, and whether they are used in isolation or if interaction is required with other artefacts. Finally, opportunities for redistribution of knowledge are proposed with a limitation that these are not

implemented; therefore, their appropriateness and success cannot be validated.

Detailed analysis of the design of the *preparation checklist* has not been conducted. However, design considerations are discussed in *Chapter 7: Discussion and Conclusions*. A summary description of the findings is provided in *Table 6-5: Summary of Artefact Flow* below, which describes the interactions between the principle artefact and mediating artefacts. Specific notes and issues are also highlighted in the table.

Table 6-5: Summary of Artefact Flow

<p>Summary</p> <p>The principal artefact is the preparation checklist. However, the preparation checklist was not explicitly referenced during observations.</p> <p>Each of the eighteen items on the <i>preparation checklist</i> is represented as a <i>goal</i>. For each goal to be achieved, interactions must occur between individuals referred to as <i>actors</i>, and between other artefacts referred to as <i>mediating artefacts</i>. The distribution of knowledge between the actors is supported by the principal and mediating artefacts in the operating theatre environment. Other knowledge gained from experience appears to be required in the distribution of knowledge to facilitate preparation of the operating theatre for hip arthroscopy surgery.</p>
<p>Details</p> <p><u>Access to Artefacts</u></p> <p>There are multiple artefacts available to the theatre team members. Artefacts are mostly shared as very few were identified to be contained for access by an individual theatre team member.</p> <p>During observations, artefacts appear to be widely dispersed across the operating theatre environment and do not represent any logical organisation or links with each other. However, after a few observations, the findings indicate that access to artefacts and interactions with the artefacts is a fluid part of a wider complex joint cognitive system.</p>

Table 6 5: Summary of Artefact Flow - Continued

<p>Notes • Any notable aspects related to artefacts</p> <p>Special policies, procedures, or practices were not visibly linked to the observed artefacts. Additional artefacts, such as hospital policies and NICE guidelines are not accessible but must be coordinated.</p> <p>Artefacts displayed on-screen were often printed and displayed on a white board on the operating theatre wall.</p>
<p>Issues • Any aspects impacting workload and performance</p> <p>The principal artefact was easily accessible in a folder within the operating theatre; however, it was not always visible.</p> <p>During observations, the patient list was physically held by an actor; therefore, this restricted its visibility for other actors. This was only resolved when the patient list was displayed on the white board on the operating theatre wall.</p>

6.11 Discussion

The findings show that by applying an existing theoretical framework to the study of how a surgical checklist is used, this contributes a novel insight into WAD in the operating theatre environment.

DCog and DiCoT frameworks enabled the structured identification of interactions between people, artefacts, and tools by providing a representation of WAD within a theoretical framework. Hazlehurst et al support the application of DCog to explain these interactions when investigating WAD.²⁷⁵ However, guidance for applying the methodological and analytical approach was limited, and additional source material was required to ensure that data capture was thorough. Additionally, an approach to the in-depth analysis was required to triangulate the vast amount of data generated by multiple sources.

Identification of existing knowledge distribution within a complex environment aids understanding of what works in the current joint cognitive system and what needs to be redesigned through the redistribution of knowledge. The findings show that even with the implementation of an informal checklist as a cognitive aid to support preparation, complex interactions between multiple actors, multiple artefacts, and tools are still required. Viewing the operating theatre in terms of a joint cognitive system demonstrates how information is distributed internally across the operating theatre and highlights external influencing factors.

A key finding relates to how goals are currently performed in an implicit manner. The theatre team members work in unison to complete shared goals without the need to explicitly state responsibility or role. However, further analysis highlights that the principal artefact could be used more explicitly to support the quality of the preparation goals. The scrub nurse is perceived to be responsible for the accurate preparation of the operating theatre, although no explicit leadership was displayed in terms of instructions given to the supporting theatre team members. In addition, the *preparation checklist* is neither used for preparation of each surgical operation, nor is it used daily.

This has the potential to degrade its use as a cognitive aid, resulting in its content being committed to memory which is fallible to the limitations it is intended to support. The findings show that goal completion is assumed by the physical representation of the operating theatre environment, specifically related to the layout and active sterile area. Experience and internal cognitive processing are necessary to understand this status. Utilising the preparation checklist for confirmation of goals and crosschecking is almost non-existent.

A limitation to this study is the investigation of only a subset of the entire hip arthroscopy surgical process flow in the operating theatre. It is not possible to identify if other factors influence preparation for surgery, such as organisational issues, resources etc., which are external to the operating theatre environment. The findings do not fully explain the theatre team members' understanding of how to complete preparation tasks; structured interviews would complement these findings. In addition, access to other artefacts such as clinical guidelines etc. may impact interactions. However, these were not immediately visible within the operating theatre and were not further investigated.

Based on these findings, multiple opportunities are suggested for the redistribution of knowledge; details can be found in *Appendix J – Preparation Checklist Items*. Suggesting possible changes to the joint cognitive system are not validated through this study. The changes are suggested as opportunities for redesign which require further consideration, trial, and validation. The redesign suggestions are not intended as design guidelines. Future work is suggested in *Chapter 7: Discussion and Conclusions*.

Chapter 7 Discussion and Conclusions

7.1 Overview of the Chapter

In this chapter, the research aim and research questions will be revisited with a summary of the key findings of this research. An overview of the contribution of this research to the research area will be provided. In addition, the limitations of this research will be highlighted, and future work will be proposed to improve and expand on this research. Finally, recommendations will be proposed to inform the redesign of existing surgical checklist use and the future adoption of surgical checklists.

7.2 Declaration

None to declare for this chapter.

7.3 Review of the Research Aim

The overall research aim was to investigate the use of surgical checklists by theatre teams in the operating theatre, thereby contributing evidence to the current state of knowledge in this research area. This research aimed to understand how existing surgical checklists are used in practice in UK hospitals by investigating the overarching research question:

How do theatre teams currently use surgical checklists in practice?

In order to address this question, current knowledge was investigated by review of the existing literature (*Chapter 3: A Scoping Review*), and current practice was investigated by two empirical studies (*Chapter 5: Empirical Study I* and *Chapter 6: Empirical Study II*).

7.4 Summary of the Key Findings

Detailed discussions are contained within the relevant chapters: *Chapter 3: A Scoping Review*, *Chapter 5: Empirical Study I*, and *Chapter 6: Empirical Study II*. This section provides a summary of the key findings related to the three questions investigated in this research.

In *Chapter 3: A Scoping Review*, the following research question was addressed:

RQ1: What methodologies are applied to investigate how surgical checklists are used in practice, and what are the associated outcome measures?

The key findings from *Chapter 3: A Scoping Review* indicate that:

1. in the last decade, extensive work has been conducted to investigate surgical checklist use. Various methodological approaches have been employed such as quantitative, qualitative, and mixed-methods, and currently no standardised method of investigation is proposed;
2. studies investigating surgical checklist use focus mostly on quality improvement outcome measures and impacts of surgical checklist use;

3. from the identified studies, the utilisation of a theoretical framework to describe surgical checklist use in practice is limited;
4. none of the identified studies investigate unofficial surgical checklists, highlighting a significant gap in the literature and in current knowledge; and
5. minimal evidence is available to comprehensively describe surgical checklist use in terms of WAI and WAD.

In *Chapter 5: Empirical Study I*, the following research question was addressed:

RQ2: What is the current level of compliance to the WHO SSC in practice in UK hospital operating theatres?

The key findings from Chapter 5: *Empirical Study I* indicate that:

1. theatre team members frequently use parts of the WHO SSC, specifically the time-out section. However, adherence to completion of the WHO SSC in its entirety is less than optimal;
2. the overall quality of performance in conducting the WHO SSC is low;
3. overall WHO SSC compliance is not as expected, or not as reported in UK mandatory audits; and
4. audits and compliance targets do not provide a representative account of how the WHO SSC is being used in current practice.

In *Chapter 6: Empirical Study II*, the following research question was addressed:

RQ3: How do theatre teams use a surgical checklist to prepare the operating theatre for hip arthroscopy surgery?

The key findings from Chapter 6: *Empirical Study II* indicate that:

1. unofficial surgical checklists exist in current practice in UK hospital operating theatres;
2. investigating surgical checklist use in practice is challenging due to the complexities of WAD;

3. applying a theoretical framework to investigate surgical checklist use guides the methodological approach;
4. applying a theoretical framework to investigate surgical checklist use is limited in guidance for an analytical approach;
5. knowledge distribution between theatre team members is primarily implicit and reliant on experience of the theatre teams;
6. utilising surgical checklists as a cognitive artefact requires a complex understanding of the interactions between people and other artefacts internal and external to the operating theatre;
7. limited tacit knowledge is available to describe surgical checklist use and WAD; and
8. extensive opportunities for the redesign of current surgical checklist use were identified, which contribute to the existing knowledge, potentially benefiting future work.

7.5 Research Contributions

Patient safety issues remain a significant challenge to global healthcare.³¹² The delivery of safe surgery is an area of increasing importance, which is illustrated through the growing body of research and the active debate surrounding the adoption and continued use of surgical checklists. To date, no conclusive evidence is provided for or against their use in surgical settings. The findings of this research do not intend to address this question; however, this research provides evidence to support and advance the current state of knowledge. Through investigating current practice, WAD is made visible and allows for evidence-based interpretation of the research findings. The findings provide an important contribution to the understanding of surgical checklist use in current practice, specifically in UK hospital operating theatres.

This research demonstrates that many factors related to surgical checklist use in practice are still unknown. Over the last decade, there has been an influx of work in this area, which has advanced knowledge related to what is not working in current practice. Although the benefits of surgical checklists have been discussed in existing literature, limited evidence is provided to

specifically identify what is working in current practice. This research highlights a significant contribution to the understanding of surgical checklists by presenting the complexities of their use in practice. In addition, this research adds a novel insight into surgical checklist use by applying an established theoretical framework to investigate WAD.

Factors were identified in this research that may impact how surgical checklists are used in practice; currently, there is no evidence to illustrate the complete scope and variety of surgical checklists used in practice. This research illustrates that both official and unofficial surgical checklists co-exist in surgical settings and identifies a significant knowledge gap. This research also highlighted that no clear distinction has been made between surgical safety checklists used for critical safety checks and other types of surgical checklists used for daily checks. In addition, visibility of unofficial surgical checklists is lacking. Therefore, this research identifies a knowledge gap which needs to be addressed to understand the links between surgical checklists to ensure that WAI and WAD are aligned.

7.6 Limitations and Future Work

In research, limitations are inevitable and must be highlighted to ensure that they have been appropriately considered within the research. A number of limitations were encountered in relation to the review of existing literature, conducting empirical research in a naturalistic environment, and the generalisability of this research. Specific limitations are provided below with suggestions for how these can be addressed to benefit future work.

7.6.1 Interpreting Existing Work

Existing research contributes knowledge to the research area and aids in the identification of research gaps. In *Chapter 3: Scoping Review*, numerous studies were identified, which aimed to investigate surgical checklist use; however, the findings of the scoping review identified knowledge gaps in the existing literature. Research in this area typically focuses on investigating

surgical checklists post-implementation without a clear account of how the surgical checklists are adopted, i.e. specific details related to local modifications of the surgical checklist and information related to the training of personnel in how to use the surgical checklist.

Detailed descriptions of implementation strategies would aid further understanding of potential barriers to surgical checklist success. A key factor highlighted as a barrier is the top-down versus bottom-up approach to surgical checklist implementation. The NHS has a predominantly top-down approach to implementing quality improvement projects;³¹³ this type of approach has been raised as leading to poor buy-in from clinical staff.³¹⁴ The mandated implementation of the WHO SSC has been found to result in some users acknowledging the stated purpose; however, they also reported being left with a feeling that the implementation was not driven by a local need.³¹⁴

When new processes are imposed without end user buy-in, this can hinder feelings of ownership.²³⁵ When a bottom-up approach is applied, clinical engagement can lead to psychological ownership, which has been linked with acceptance in adopting interventions such as surgical safety checklists.^{235,315} Engaging multiple users in the implementation process can lead to collective psychological ownership, which can have a positive impact on the entire operating theatre team as this increases their perceptions of checklist integration with their needs and work processes.³¹⁶

The WHO SSC adaptation guide specifies that a collaborative approach should be adopted to modify the WHO SSC, involving representatives from all user groups who may use it, i.e. nurses, anaesthesiologists, surgeons, and others. The WHO emphasises the importance of this approach for ensuring that appropriate modifications are made. This approach also ensures that users experience ownership of the checklist in order to adopt its use for sustainable changes in practice.¹²⁶ Organisations such as *Lifebox* who are committed to surgical checklist success propose that a balanced approach between top-down and bottom-up surgical checklist implementation should lead to lasting change.³¹⁷

Therefore, interpreting existing research and how it relates to a complete understanding of surgical checklist use in practice should be treated with some caution. The following points summarise limitations of the scoping review approach and propose future work:

- During the scoping review methodology, many types of surgical checklist were identified that may not be applied to surgical settings such as the WHO SSC modified for radiology³¹⁸ and the WHO SSC modified for dental surgery and other surgical checklists in dental surgery.³¹⁹ Future work may be expanded to encompass the investigation of surgical checklists in these settings.
- The scoping review provided a summary of key concepts related to the investigation of surgical checklist use, i.e. identification of the methodologies and associated outcome measures. This provided adequate information to establish and interpret the scope of existing work in this research area. However, future work would benefit from extending the scoping review approach to synthesise the data and critically appraise the evidence in a systematic manner. In order to improve the reporting quality of the scoping review, additional guidance could be utilised, such as the newly published 'Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) checklist.'³²⁰
- The scoping review findings may be limited by additional factors:
 - a lack of robust descriptions of methods and outcome measures may have resulted in incorrect categorisation;
 - ensuring a complete set of literature is difficult to validate in a scoping review; and
 - inclusion of literature is more complex in a single researcher approach. Therefore, this research would benefit from the addition of an independent reviewer to screen literature against the inclusion criteria.¹³³
- Further validation of the scoping review findings would strengthen this research and application of an additional literature review methodology may also further advance knowledge of existing work.

7.6.2 Conducting Empirical Research

Activity in the operating theatre is difficult to comprehensively analyse from outside sources; understanding and interpreting WAD is maximised when observed in a naturalistic environment. Observation is an established method for studying WAD. However, a limitation of this research was the constraints of studying theatre team performance and interactions isolated within the operating theatre. The contributions and influences of the wider system are essential for comprehensively understanding and interpreting what is observed. The following points summarise these limitations and propose future work:

- A significant amount of WAD is implicit; little WAD is made explicit and tacit knowledge is limited. Therefore, ensuring a complete understanding of WAD is difficult via observation alone. Therefore, future work would benefit from additional and complimentary methodological approaches such as document analysis, interviews, and focus groups.
- This research investigated WAD in a mixed-methods approach, which was considered necessary to firstly establish an understanding of current practice, and secondly to investigate current practice in a more 'organic' ethnography approach; this was further supported by applying a theoretical framework to guide a deeper understanding of how surgical checklists are used in practice by providing a descriptive account of WAD. This approach benefits this research area as the operating theatre is a dynamic and complex environment, and it is not possible to observe 'A' and conclude 'B'; therefore, a holistic approach to an organic environment is appropriate. Mixed methods add dimension to the study of practice by enabling greater flexibility rather than applying a restrictive quantitative approach; however, this approach also limits the robustness and replicability of this research. The ability to replicate exploratory research is one of the biggest challenges to studying practice. However, a naturalistic setting is required for the study of practice. Many aspects of applying this type of research cannot be controlled in a systematic scientific approach.

Future work would benefit from further consideration of this limitation for a more standardised approach to reduce the variance in methodological approaches and ranges of outcome measures. However, the study of practice lacks standardisation, which makes it difficult to train observers and replicate research in other hospitals.

Specific limitations related to *Empirical Study I* and future work are proposed:

- *Empirical Study I* was conducted within the scope of the S3 Project. There were limitations to *Empirical Study I*, which would benefit both this research and the work of the S3 Project if addressed in future work. Firstly, prior to data collection, more information could have been gathered to establish how the WHO SSC was implemented at each hospital. This would have improved the quality of the findings by providing a link between what was expected (WAI) and what was observed (WAD).
- The S3 Project research team made a collective decision not to observe the sign-in section of the WHO SSC. This was a practical approach out of consideration for patient comfort. However, the addition of this data would have strengthened the findings of *Empirical Study I* and the contribution to knowledge. However, ethics approval may have been impacted, and patient consent may have been required. Future work in this area should consider methods to observe the sign-in section by similar methods as the time-out and sign-out. Other approaches such as a retrospective video analysis may be difficult for ethics approval due to patient privacy and comfort factors. Alternative methods such as sign-in observed by a single observer in the induction room could be explored.
- The observational data collected for the S3 Project was extensive. Opportunities to collect additional information related to the WHO SSC use was explored such as a communication analysis. However, any additional data collection was considered excessive in the wider scope of the S3 Project. Therefore, this limited the full potential of data

collected during *Empirical Study I*. This would be an important consideration in future work.

Specific limitations related to *Empirical Study II* and future work are proposed:

- *Empirical Study II* was guided by a methodological approach, although knowing how to capture a true representation of reality is more complex than in traditional scientific approaches. Practice based research and more specifically ethnography approaches often require initial exposure to the study idea, allowing for an understanding phase and refinement of data collection methods in an iterative approach. The S3 Project enabled exposure to the selected research area and highlighted other pertinent areas in the surgical flow. Data analysis further supports additional areas that would benefit from supplementary exploration in order to strengthen the current findings. Therefore, in this type of research, it is important to create opportunities to pause data collection, analyse preliminary findings, and have additional time to expand on relevant areas. Within the time constraints of PhD research, this is not always possible but is an important consideration for future work.
- The research methods applied to *Empirical Study II* were labour intensive. The single observer approach was accepted practice; however, the scope of the study required control to ensure that quality data was captured. Therefore, this methodology is suitable for a limited scope and can only be applied to a limited time exposure. In addition, this would generate a vast amount of data. Interpreting the findings requires caution not to overgeneralise or present conclusive evidence.
- Any recommendations related to *Empirical Study II* are primarily applicable for use in hip arthroscopy surgery but may be transferable for application to other surgical specialties. Future work could address this transfer of knowledge.

Further limitations are related to more in-depth links that could have been made between *Empirical Study I* and *Empirical Study II*. Suggested future work includes:

- observing the same parameters in both studies;
- identifying similarities and differences between the two surgical checklists;
- conducting a communication analysis in each study; and
- conducting structured interviews.

7.6.3 Generalising the Research Findings

Several limitations of the research were identified related to the scope of the research and the impact on the generalisability of the research findings. The following points summarise these limitations and propose future work:

- This research investigated two types of surgical checklists in use in current practice in UK hospital operating theatres: one known, mandatory surgical checklist and one unknown, unofficial surgical checklist. The findings of this research cannot be generalised to how all surgical checklists are used in practice; however, future work would benefit from including a wider range of surgical checklists.
- A total of five hospitals participated in this research, all of which were part of NHS England. Therefore, the generalisability of the findings to hospitals across the UK and worldwide is limited. Future work would benefit from including a wider range of hospitals.
- In *Empirical Study I*, observations were conducted across various surgical specialties; however, in *Empirical Study II*, observations were limited to one type of surgical specialty. Therefore, generalising the findings of this research is limited. Future work would benefit from including a wider range of surgical specialties in all empirical investigations.

Overall, defining the exact mechanisms by which surgical checklists demonstrate improvements is inconclusive in the existing literature. The heterogeneity of the included studies is a major limitation due to variations in study design, study populations, economic circumstances, methodological

approaches, and study quality.^{42,201,205,206,208,237,321} These issues limit the capability to systematically analyse and interpret reported data. Determining the various effects reported and separating the impact of surgical checklist implementation on each end-point outcome measure is complex.²³⁷ In addition, the generalisability of the results is questionable as there is less evidence from low and middle-income countries to demonstrate the varied environments in which surgical checklists are implemented.³²¹ When positive impacts are reported, the data must be interpreted with caution. Positive results may be related to wider quality of care practices and the influence of additional mechanisms supporting surgical checklist implementation.³²¹

Establishing causal links between surgical checklist implementation and the impact on numerous outcome measures is difficult due to the heterogeneity and varying quality of studies. The need for further studies was frequently stated in existing literature, and these studies would benefit from the standardisation of study design and reporting.²⁰⁶ Considerations for future work include:

- baseline assessments of outcome measures;²⁰⁶
- improving the quality of studies with a surgical checklist implementation phase to allow time for new processes to be embedded;²⁰⁶
- validated measuring tools;^{206,237} and
- extending the length of studies to assess the longitudinal impacts of surgical checklist implementation.^{201,206,237}

Without improvements in heterogeneity and the quality of studies, it is unlikely that causal benefits associated with surgical checklist use will be evident.^{42,206}

7.6.4 The Future of Surgical Checklist Use

Many aspects of this research cross over with the patient safety improvement efforts of others adopting approaches in HF, Safety I, Safety II, and Resilient Engineering,^{247,248,322-324} which illustrates a growing body of work in this prevalent research area. The WHO and other organisations such as LifeBox³²⁵

continue to focus on surgical checklists as improvement initiatives for safer surgery. Collectively the findings continue to contribute to the advancement of knowledge. However, due to the complexities of WAD in the surgical environment and the influence this may have on how surgical checklists are used in practice, further evidence is needed. The traditional method of adopting a checklist as a solution to a problem requires specific attention in surgical settings. In this environmental context, the traditional approach may be too narrow and does not fully consider the wider context and complexity of the environment. Bosk et al support the need for further research to advance the current state of knowledge of understanding how and why surgical checklists work, emphasising that without this knowledge, the extensive adoption of surgical checklists could have a detrimental impact on patient safety.⁴⁴

As technology advances in any industry, there is a tendency to utilise modern advancements and apply them to areas of practice; for example, in aviation the paper-based checklist advanced to a highly integrated and intelligent checklist, which is now available on all advanced flight decks. In aviation, paper-based and technology-based checklists coexist as part of the socio-technical system.⁸² The findings of this research highlight potential for the redistribution of knowledge from the existing surgical checklists to other artefacts; however, the suggestions focus on what is currently available and possible within the operating theatre rather than introducing the concept of technology driven cognitive artefacts. Suggestions have been made that it is time for the paper-based surgical checklist to advance by utilising technology.³²⁶

7.7 Recommendations

Recommendations to improve surgical checklist use are proposed based on the findings of this research and the identified limitations.

7.7.1 Recommendations for the Healthcare Industry

The findings of this research contribute to proposed recommendations for the healthcare industry. The following recommendations are provided for consideration:

- documenting current practice to support theatre team members' understanding of current practice;
- documenting current practice to aid training of new theatre team members;
- creating evidence-based scenarios to support context-based training of new personnel and recurrent training of existing personnel;
- documenting current practice to benefit standardisation; and
- documenting practice for researchers to advance the learning curve prior to conducting research in surgical settings.

7.7.2 Recommendations for the WHO

The findings of this research contribute to proposed recommendations for the WHO. It is difficult to establish the future strategy of the WHO; therefore, the following recommendations are outlined in lieu of this information:

- revisiting the WHO SSC based on empirical evidence since implementation;
- establishing the extent of modifications to the WHO SSC;
- providing design guidelines for modifications to the WHO SSC; and
- updating the WHO website and media accordingly to ensure dissemination of the most recent guidance and information.

7.7.3 Recommendations for Healthcare Policy Makers

The findings of this research contribute to proposed recommendations for policy makers. Policy makers could support both research and the healthcare industry by addressing multiple aspects. The following recommendations are provided for consideration:

- providing definitions and guidelines for the differences between surgical checklists and surgical safety checklists;
- providing guidelines on the adoption of unofficial surgical checklists;
- providing definitions for compliance targets related to the quality of surgical checklist use; and
- providing a standardised audit strategy of evaluating surgical checklist use.

7.7.4 Reflections on My Research Journey

This research has been an insightful, informative, and rewarding experience. My exposure to other high-risk industries influenced my early ideas about what to expect in healthcare. Initially, I expected to understand the industry in a structured approach; however, I was quickly aware of the complexity of healthcare and the mass of interdependencies during a patient's pathway. Patient safety research spans many aspects of healthcare; however, surgery was an area that captivated my attention. My main challenge came with identifying a limited research scope. It was natural for me to want to apply my knowledge from other industries and learn everything I could about surgery, i.e. the theatre team roles and responsibilities, the operating theatre environment, and the surgical process flow. However, the S3 Project and the support of my colleagues provided an opportunity to gain knowledge, which guided my selected research area.

During the S3 Project training period, I recognised that transfer of knowledge would be limited without a foundation of understanding the highly complex operating theatre environment. I learnt that it was impractical to cover a wide scope when embarking on empirical research in a naturalistic setting. This

limitation is mostly due to time constraints and the required resources. Exposure to an average day in surgery highlighted a complex web of interdependencies and confirmed the significance of contributing to the knowledge of current practice. As an HF specialist, it would have been practical and relevant to evaluate surgical checklists, i.e. identifying whether they are fit for purpose, appropriately designed and implemented, and sustainable. However, the S3 Project and the PhD enabled me to expand on my knowledge, grow as a researcher, and gain additional skills for my profession. Contributing knowledge which was focused on quality and relevance to a current pertinent patient safety area was a priority.

Throughout my PhD, I have faced many challenges, mostly related to the application of research in a practical work setting. As an HF consultant, I was often given the freedom to adjust my approach real-time, as required. However, in the application of research, I learnt to adapt my skills to follow a methodological approach. I am grateful for the opportunity to work with many inspiring people, and I am particularly appreciative of the theatre teams who participated in this research as without them, the research would not have been possible. Furthermore, observing the theatre teams enabled me to gain an advanced understanding of WAD in surgical settings.

During the final phase of my PhD, I am considering the next steps to continue in this research area. There are multiple avenues to pursue based on the findings of this work. My first aim is to publish *Empirical Study II* as this work provides a novel insight into WAD by emphasising the use of unofficial surgical checklists. Therefore, publishing the findings of this study would contribute to awareness of unofficial checklists and new investigations into their use in surgical settings. From my experience, I advocate the use of checklists in high-risk industries, and this research has enabled me to value the benefits that have been found from checklist adoption in surgery. However, I can now also appreciate the complexities of answering seemingly simple questions related to their use in surgery. My overall aim is to continue to contribute to patient safety improvements by applying the new knowledge from this research through academic and professional channels.

Chapter 8 Appendices

8.1 Appendix A – Boeing Model 299 Accident Summary

As discussed in *Chapter 2: Checklists*, Box 1 below provides a summary of the Boeing Model 299 accident.^{58,327}

Box 1: Boeing Model 299 Accident Summary

The experienced flight crew of the Boeing Model 299 included:

- Maj. Ployer P. Hill (Captain);
- 1st Lt. Donald L. Putt (Co-pilot);
- John B. Cutting (flight-test observer);
- Mark H. Koogler; and
- Leslie R. Tower (Boeing chief test pilot).

Observers watching the prototype flight described the initial take-off as normal. However, as the aircrafts speed increased the Model 299's nose went up much higher than normal. The aircraft stalled, turned 180 degrees, and crash landed killing two onboard.

Accident investigators determined that the aircraft had crashed due to the elevator and rudder controls locking which prevented the pilot from lowering the nose of the aircraft. Resulting in an unrecoverable stall. The crew has forgotten to disengage the locking mechanism before take-off which was controlled from inside of the cockpit.

A board of officers determined the accident was the direct cause of the elevator control being locked and not disengaged. Therefore, a "pilot error" verdict was inferred. The board stated that the relevant checks did not occur prior to take-off and it was improbable that the crash was recoverable due to the size of the aircraft and the force of the locking mechanism. To prevent another accident the Air Corps developed aviation checklists for the crew to follow checks for takeoff, flight, before landing, and after landing. Aviation checklists had been available before; however, this accident institutionalised aviation checklist use on all future flights.

8.2 Appendix B – WHO Surgical Safety Checklist

As discussed in *Chapter 2: Checklists*, the *World Health Organization Surgical Safety Checklist – First Edition*³²⁸ is presented below.

Permission authorisation for WHO copyrighted material was obtained on 08/10/2019; authorisation number 301535.

Surgical Safety Checklist

Before induction of anaesthesia

(with at least nurse and anaesthetist)

Has the patient confirmed his/her identity, site, procedure, and consent?

☐ Yes

Is the site marked?

☐ Yes

☐ Not applicable

Is the anaesthesia machine and medication check complete?

☐ Yes

Is the pulse oximeter on the patient and functioning?

☐ Yes

Does the patient have a:

Known allergy?

☐ No

☐ Yes

Difficult airway or aspiration risk?

☐ No

☐ Yes, and equipment/assistance available

Risk of >500ml blood loss (7ml/kg in children)?

☐ No

☐ Yes, and two IVs/central access and fluids planned

Before skin incision

(with nurse, anaesthetist and surgeon)

☐ Confirm all team members have introduced themselves by name and role.

☐ Confirm the patient's name, procedure, and where the incision will be made.

Has antibiotic prophylaxis been given within the last 60 minutes?

☐ Yes

☐ Not applicable

Anticipated Critical Events

To Surgeon:

☐ What are the critical or non-routine steps?

☐ How long will the case take?

☐ What is the anticipated blood loss?

To Anaesthetist:

☐ Are there any patient-specific concerns?

To Nursing Team:

☐ Has sterility (including indicator results) been confirmed?

☐ Are there equipment issues or any concerns?

Is essential imaging displayed?

☐ Yes

☐ Not applicable

Before patient leaves operating room

(with nurse, anaesthetist and surgeon)

Nurse Verbally Confirms:

☐ The name of the procedure

☐ Completion of instrument, sponge and needle counts

☐ Specimen labelling (read specimen labels aloud, including patient name)

☐ Whether there are any equipment problems to be addressed

To Surgeon, Anaesthetist and Nurse:

☐ What are the key concerns for recovery and management of this patient?

This checklist is not intended to be comprehensive. Additions and modifications to fit local practice are encouraged.

Revised 1 / 2009


© WHO, 2009

8.3 Appendix C – WHO Anaesthesia Checklist

As discussed in *Chapter 2: Checklists*, the *World Health Organization Anaesthesia Checklist*¹²⁸ is presented below.

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Anesthesia Safety Checklist



Before induction of anesthesia

Is an experienced and trained assistant available to help you with induction?

☐ Yes

☐ Not applicable

Has the patient had no food or drink for the appropriate time period?

☐ Yes

☐ Not applicable

Is there intravenous access that is functional?

☐ Yes

Is the patient on a table that can be rapidly tilted into a head-down position in case of sudden hypotension or vomiting?

☐ Yes

Equipment check:

- ☐ If compressed gas will be used, is there enough gas and a reserve oxygen cylinder?
- ☐ Anesthetic vaporizers are connected?
- ☐ Breathing system that delivers gas to the patient is securely and correctly assembled?
- ☐ Breathing circuits are clean?
- ☐ Resuscitation equipment is present and working?
- ☐ Laryngoscope, tracheal tubes and suction apparatus are ready and clean?
- ☐ Needles and syringes are sterile?
- ☐ Drugs are drawn up into labelled syringes?
- ☐ Emergency drugs are present in the room, if needed?

8.4 Appendix D – Scoping Review Concept Matrix

As discussed in *Chapter 3: Methods for Studying Surgical Checklist Use and Associated Outcomes: A Scoping Review*, the *Scoping Review Concept Matrix* is presented below.

Year	Study Source	Methods								Outcome Measure							
		Observation – Quantitative	Observation – Qualitative	Questionnaire / Survey	Focus Group	Interviews	Systematic Review	Review of Records	Video Recordings	Mortality / Morbidity	Complications	Compliance / Adherence	Team Performance	Team Perceptions	Patient Safety	Feasibility / Effectiveness	Process Improvements
2019	Belykh et al ²¹⁰							X			X						
	Schwendiman ¹³⁵	X	X			X						X					
2018	Westman et al ²¹²							X			X						
	Ziman et al ¹⁶⁸		X			X						X		X			

[illegible]

8.4 Appendix D – Scoping Review Concept Matrix - Continued

Year	Study Source	Methods								Outcome Measure							
		Observation – Quantitative	Observation – Qualitative	Questionnaire / Survey	Focus Group	Interviews	Systematic Review	Review of Records	Video Recordings	Mortality / Morbidity	Complications	Compliance / Adherence	Team Performance	Team Perceptions	Patient Safety	Feasibility / Effectiveness	Process Improvements
2016	de Jager et al ²⁰⁰						X			X	X						
	Dharampal et al ¹⁹⁶					X								X			
	Lacassie et al ¹³⁶	X								X							
	Mayer et al ¹³⁷	X								X	X						
2015	Jammer et al ²¹⁵							X		X							
	Lepanluoma et al ¹³⁸	X						X			X						
	Haugen et al ¹³⁹	X								X	X						

8.4 Appendix D – Scoping Review Concept Matrix - Continued

Year	Study Source	Methods								Outcome Measure							
		Observation – Quantitative	Observation – Qualitative	Questionnaire / Survey	Focus Group	Interviews	Systematic Review	Review of Records	Video Recordings	Mortality / Morbidity	Complications	Compliance / Adherence	Team Performance	Team Perceptions	Patient Safety	Feasibility / Effectiveness	Process Improvements
2015	Haugen et al ²³¹				X									X			
2014	Saturno et al ¹⁴⁰	X						X				X		X			
	Urbach et al ¹⁴¹	X								X	X						
	Kawano et al ³³⁰			X								X		X			
	Cullati et al ³³¹			X								X		X			
	Lepanluoma et al ¹⁸⁴			X											X		
	Ryan et al ¹⁴²	X									X						X

8.4 Appendix D – Scoping Review Concept Matrix - Continued

[illegible]

8.4 Appendix D – Scoping Review Concept Matrix - Continued

Year	Study Source	Methods								Outcome Measure							
		Observation – Quantitative	Observation – Qualitative	Questionnaire / Survey	Focus Group	Interviews	Systematic Review	Review of Records	Video Recordings	Mortality / Morbidity	Complications	Compliance / Adherence	Team Performance	Team Perceptions	Patient Safety	Feasibility / Effectiveness	Process Improvements
2013	Rydenfält et al ¹⁷⁰		X									X		X			
	Poon et al ¹⁷¹		X									X		X			
	Sparks et al ³³⁷		X									X		X			
	Hannam et al ³³⁸		X									X		X			
2013	Cullati et al ¹⁷⁴		X									X		X			
	Lubbeke et al ¹⁴³	X								X	X						
	Braaf et al ¹²⁵		X		X	X										X	
	Haugen et al ³³⁹			X								X		X			

8.4 Appendix D – Scoping Review Concept Matrix - Continued

Year	Study Source	Methods								Outcome Measure							
		Observation – Quantitative	Observation – Qualitative	Questionnaire / Survey	Focus Group	Interviews	Systematic Review	Review of Records	Video Recordings	Mortality / Morbidity	Complications	Compliance / Adherence	Team Performance	Team Perceptions	Patient Safety	Feasibility / Effectiveness	Process Improvements
2013	Papaconstantinou et al ³⁴⁰			X								X		X			
	O'Connor et al ³⁴¹			X								X		X			
	Fargen et al ³⁴²			X							X		X				
	Flint et al ²¹⁶							X			X						
	Hommelstad et al ²¹⁷							X			X						
	Kubilay et al ²¹⁸							X			X						
	Russ et al ²⁰⁶						X						X				
	Aveling et al ¹⁸⁷		X			X		X				X		X			

8.4 Appendix D – Scoping Review Concept Matrix - Continued

Year	Study Source	Methods								Outcome Measure							
		Observation – Quantitative	Observation – Qualitative	Questionnaire / Survey	Focus Group	Interviews	Systematic Review	Review of Records	Video Recordings	Mortality / Morbidity	Complications	Compliance / Adherence	Team Performance	Team Perceptions	Patient Safety	Feasibility / Effectiveness	Process Improvements
2013	Pickering et al ¹⁴⁴	X										X	X				
2012	Levy et al ¹⁷⁶		X									X		X			
	Sheena et al ³⁴³		X									X		X			
	Bliss et al ³⁴⁴	X									X						
	van Klei et al ³⁴⁵	X								X	X						
	Fourcade et al ²⁸⁹	X		X		X		X				X		X		X	
	Healy et al ³⁴⁶					X							X				

8.4 Appendix D – Scoping Review Concept Matrix - Continued

Year	Study Source	Methods								Outcome Measure							
		Observation – Quantitative	Observation – Qualitative	Questionnaire / Survey	Focus Group	Interviews	Systematic Review	Review of Records	Video Recordings	Mortality / Morbidity	Complications	Compliance / Adherence	Team Performance	Team Perceptions	Patient Safety	Feasibility / Effectiveness	Process Improvements
2012	Rahman et al ²²²							X			X						
	Zuckerman et al ³⁵⁰						X								X		
	Borchard et al ³⁰⁰						X					X				X	
2011	Spence et al ³⁵¹		X		X							X			X		
	Vogts et al ³⁵²	X										X		X			
	Styer et al ¹⁷⁹		X												X		X
	Sewell et al ³⁵³	X		X						X	X	X	X				

8.4 Appendix D – Scoping Review Concept Matrix - Continued

Year	Study Source	Methods								Outcome Measure							
		Observation – Quantitative	Observation – Qualitative	Questionnaire / Survey	Focus Group	Interviews	Systematic Review	Review of Records	Video Recordings	Mortality / Morbidity	Complications	Compliance / Adherence	Team Performance	Team Perceptions	Patient Safety	Feasibility / Effectiveness	Process Improvements
2011	Lingard et al ³⁵⁸	X											X				
	Ko et al ³⁵⁹						X							X			
	Askarian et al ¹⁵¹	X									X						
	de Vries et al ³⁶⁰							X				X				X	
2010	Lyons ³⁶¹	X									X						X
	Weiser et al ³⁶²	X								X	X	X					
	de Vries et al ¹⁵⁴	X								X	X	X					

8.4 Appendix D – Scoping Review Concept Matrix - Continued

Year	Study Source	Methods								Outcome Measure							
		Observation – Quantitative	Observation – Qualitative	Questionnaire / Survey	Focus Group	Interviews	Systematic Review	Review of Records	Video Recordings	Mortality / Morbidity	Complications	Compliance / Adherence	Team Performance	Team Perceptions	Patient Safety	Feasibility / Effectiveness	Process Improvements
2010	de Vries et al ⁹⁰ (SURPASS)	X															X
	Papaspyros et al ¹⁵⁶	X				X							X	X	X		
	Nilsson et al ¹³⁶³			X										X			
	Einav et al ¹⁵⁷	X												X	X		
	Vats et al ¹³⁶⁴	X								X	X	X					
	Norton et al ¹⁵⁸	X										X	X				X
	Buzink et al ¹⁵⁹	X													X	X	
	Thomassen et al ¹⁶⁰	X											X				X

8.4 Appendix D – Scoping Review Concept Matrix - Continued

[illegible]

8.4 Appendix D – Scoping Review Concept Matrix - Continued

Year	Study Source	Methods								Outcome Measure							
		Observation – Quantitative	Observation – Qualitative	Questionnaire / Survey	Focus Group	Interviews	Systematic Review	Review of Records	Video Recordings	Mortality / Morbidity	Complications	Compliance / Adherence	Team Performance	Team Perceptions	Patient Safety	Feasibility / Effectiveness	Process Improvements
2008	Lingard et al ⁴⁷	X											X				
	Verdaasdonk et al ¹⁶⁶	X															X
	Rosenberg et al ¹³⁶⁵	X									X	X					

8.5 Appendix E – S3 Project Ethics Approval

As discussed in *Chapter 4: Research Process*, a scanned copy of the S3 *Project Ethics Approval* is presented below.

COPY

NHS
National Research Ethics Service
Oxfordshire REC A
2nd Floor, Astral House
Chaucer Business Park
Granville Way
Bicester
OX26 4JT
Telephone: 01869 604077
Facsimile: 01869 604055

01 May 2009

Mr Peter McCulloch
Reader in Surgery
University of Oxford
Nuffield Department of Surgery
6th Floor, John Radcliffe Hospital
Oxford
OX3 9DU

Dear Mr McCulloch

Full title of study: An industrial quality improvement approach to patient safety in surgery
REC reference number: 09/H0604/39

Thank you for your letter of 30 March 2009, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Vice-Chair, Ms Sara Owen.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Ethical review of research sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

For NHS research sites only, management permission for research ("R&D approval") should be obtained from the relevant care organisation(s) in accordance with NHS research governance arrangements. Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at <http://www.rdforum.nhs.uk>.
Where the only involvement of the NHS organisation is as a Participant Identification

This Research Ethics Committee is an advisory committee to South Central Strategic Health Authority
The National Research Ethics Service (NRES) represents the NRES Directorate within
the National Patient Safety Agency and Research Ethics Committees in England.

Centre, management permission for research is not required but the R&D office should be notified of the study. Guidance should be sought from the R&D office where necessary.

Sponsors are not required to notify the Committee of approvals from host organisations.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Letter from Sponsor	University of Oxford	17 February 2009
Covering Letter		12 February 2009
Protocol	2	12 February 2009
Investigator CV	Peter McCulloch	
Application		16 February 2009
Response to Request for Further Information		30 March 2009
Participant Consent Form: Staff	2	30 March 2009
Participant Information Sheet: Staff	3	30 March 2009
Participant Information Sheet: Patients	3	30 March 2009
Grant Application and supporting documentation		
Participant Consent Form: Patients	1	12 February 2009

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Now that you have completed the application process please visit the National Research Ethics Website > After Review

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

The attached document "After ethical review –guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

We would also like to inform you that we consult regularly with stakeholders to improve our service. If you would like to join our Reference Group please email referencegroup@nres.npsa.nhs.uk.

09/H0604/39

Please quote this number on all correspondence

With the Committee's best wishes for the success of this project

Yours sincerely

Dr Brian Shine
Chair

Email:

Enclosures: "After ethical review – guidance for researchers"

Copy to: Ms Heather House, University of Oxford

Bethan Bishop, Heart of England NHS Foundation Trust

8.6 Appendix F – S3 Project Hip Arthroscopy Protocol Booklet

As discussed in *Chapter 5: Empirical Study I*, a scanned copy of the *S3 Project Hip Arthroscopy Protocol Booklet* is presented below.

V2.7 07.12.10	Date: Active / Control
SAFER SURGICAL SERVICES	
Knee Arthroscopy	
CASE SUMMARY SHEET	
PRIVATE & CONFIDENTIAL	

V2.7 07.12.10

1. Pre-operative questions to the operating surgeon

- a. On a scale of 0 – 100 (100 being the **MOST**), how confident are you that this patient will have a satisfactory long-term result?

i. Pre-operative: _____

- b. On a scale of 0 – 100 (100 being **MOST**), how confident are you that this patient will have an uncomplicated post operative course?

i. Pre-operative: _____

- c. How would you rate the difficulty of this operation? routine complex difficult

- d. Any other relevant information?

V2.7 07.12.10

Site: NOC UHCW KGH RUGBY Theatre number _____

Surgical observer: ER MH Human Factors observer: LM SP KC

Listed op: left / right _____

Order on list: ____/____ Order performed: ____/____ Reason for change: _____

Foreign key : _____ male female

1st surgeon _____ anaesthetist _____ scrub nurse _____

2nd surgeon _____ ODA/P _____ circ. Nurse _____

sales rep _____ others _____

Staff training during case: Y / N

Surgeons Anaesthetists ODA Scrub Nurse Circulating Nurse

Pre-list briefing: Y / N lead by: AN CN SN S1 S2

3

V2.7 07.12.10

2. Pre operative preparation

a. Patient in to theatre :

- b. Ventilation configured
- c. Monitoring configured
- d. Skin prepped
- e. Prep of knee up to tourniquet
- f. Draping....

Change of gloves

3. Scrub team preparation

- a. Set up of instrument table
- b. Scrub nurse sets up
 - i. Camera within a sterile plastic sheath
 - ii. Probe connected to camera
 - iii. Light source connected
 - iv. Scrub nurse checks white balance
- c. Skin instruments
- d. Laminar flow discipline

4. Tourniquet

- a. Leg elevated, tourniquet inflated
- b. Time and pressure noted on preparation board

:

4

V2.7 07.12.10

5. WHO form (time out)

- a. All information communicated? Y / N
- b. All team present? Y / N
- c. Active participation? Y / N
- d. Lead by;
 - i. Anaesthetist
 - ii. Circulating Nurse
 - iii. Scrub Nurse
 - iv. Surgeon
- e. TEDS on? Y / N
- f. ASA
 - i. 1
 - ii. 2
 - iii. 3
 - iv. 4
- g. Antibiotics given? Y / N

TIME OUT (To be read out loud)

Before start of surgical intervention for example, skin incision	
Have all team members introduced themselves by name and role? <input type="checkbox"/> Yes	
Surgeon, Anaesthetist and Registered Practitioner verbally confirm: <input type="checkbox"/> What is the patient's name? <input type="checkbox"/> What procedure, site and position are planned?	
Anticipated critical events Surgeon: <input type="checkbox"/> How much blood loss is anticipated? <input type="checkbox"/> Are there any specific equipment requirements or special investigations? <input type="checkbox"/> Are there any critical or unexpected steps you want the team to know about? Anaesthetist: <input type="checkbox"/> Are there any patient specific concerns? <input type="checkbox"/> What is the patient's ASA grade? <input type="checkbox"/> What monitoring equipment and other specific levels of support are required, for example blood? Nurse/ODP: <input type="checkbox"/> Has the sterility of the instrumentation been confirmed (including indicator results)? <input type="checkbox"/> Are there any equipment issues or concerns?	
Has the surgical site infection (SSI) bundle been undertaken? <input type="checkbox"/> Yes/not applicable <ul style="list-style-type: none"> • Antibiotic prophylaxis within the last 60 minutes • Patient warming • Hair removal • Glycaemic control 	
Has VTE prophylaxis been undertaken? <input type="checkbox"/> Yes/not applicable	
Is essential imaging displayed? <input type="checkbox"/> Yes/not applicable	

5

V2.7 07.12.10

6. Anaesthetic

- a. GA
- b. Epidural
- c. Spinal
- d. Regional anaesthesia
 - a. Femoral
 - b. Sciatic
- e. Local anaesthetic

7. Incision & access

- a. Surgeon confirms OK to start
- b. First incision

:

6

V2.7 07.12.10

8. Knee Arthroscopy

- a. Small incision through skin
- b. Trochar insert arthroscopy port
 - i. Position of the knee at 90°
 - ii. When trochar inserted, knee straightened
 - iii. Port connected to the saline
- c. Trochar removed
- d. Arthroscope inserted
 - i. Scope will be in supra-patellar bursa
 - ii. Under patella to look for cartilage damage
 - iii. Medial compartment
 - iv. Across to the centre of the knee
 1. Look at ACL and PCL
 - v. Across to the lateral compartment
 1. Under direct vision insert port site
 2. White (large) hypodermic needle inserted
 3. Needle removed and then blade inserted
 4. Probe inserted
 - a. Used to check integrity of the lateral meniscus
 - b. ACL
 - c. PCL
 - d. Meniscus

7

V2.7 07.12.10

9. Survey and Treatment

- a. Make a plan for further intervention if needed
- b. Use tools to trim meniscus edges and make them smooth
 - i. Need suction turned on
- c. Use shaver to smooth off rough edges or to remove loose bodies

10. Washout of knee

- a. Turn saline on
- b. Pump knee full and then compress as much saline out as possible

11. Wound closure

- a. Steri-strips to arthroscopy port sites

:

- b. Do Oxford NOTECHS now

12. Dressings

- a. Mepore 'plaster'
- b. Velband
- c. Crepe
- d. Tape

8

V2.7 07.12.10

13. WHO form (sign out)

- a. All information communicated? Y / N
- b. All team present? Y / N
- c. Active participation Y / N
- d. Lead by;
 - i. Anaesthetist
 - ii. Circulating nurse
 - iii. Scrub nurse
 - iv. Surgeon

SIGN OUT (To be read out loud)

> **Before any member of the team leaves the operating room**

Registered Practitioner verbally confirms with the team:

- ☐ Has the name of the procedure been recorded?
- ☐ Has it been confirmed that instruments, swabs and sharps counts are complete (or not applicable)?
- ☐ Have the specimens been labelled (including patient name)?
- ☐ Have any equipment problems been identified that need to be addressed?

Surgeon, Anaesthetist and Registered Practitioner:

- ☐ What are the key concerns for recovery and management of this patient?

14. Time out of theatre :

15. Performed operation: left / right _____

16. Debriefing Y / N lead by: AN CN SN S1 S2

9

V2.7 07.12.10

Oxford NOTECHS

		Surgical Team	Anaesthetic Team	Nursing Team
Leadership & management	Leadership Maintenance of standards Planning and preparation Workload management Authority & Assertiveness			
Teamwork & cooperation	Team building/maintaining Support of others Understanding team needs Conflict solving			
Problem solving & decision making	Definition & diagnosis Option generation Risk assessment Outcome review			
Situation awareness	Notice Understand Think ahead			
consistent inconsistent	consistent inconsistent	inconsistent consistent	inconsistent consistent	
Behaviour compromises patient safety and effective teamwork	Behaviour in other conditions could directly compromise patient safety and effective teamwork	Behaviour maintains an effective level of patient safety and teamwork	Behaviour enhances patient safety and teamwork, a model for all other teams	

10

V2.7 07.12.10

17. Handover to Recovery

- a. Anaesthetist delivers patient to bed space
- b. Recovery nurse ready & available for receipt of patient
- c. Set up of monitoring
- d. Handover of information
 - i. Patient details Y / N
 - ii. Allergies Y / N
 - iii. Operation details Y / N
 - iv. Anaesthetic details Y / N
 - v. Analgesia plan Y / N
 - vi. Post operative plan Y / N
 - vii. Questions Y / N
- e. Drains are located safely & on suction
- f. Handover finished

:

18. General contextual comments

11

V2.7 07.12.10

19. Post-Operative questions to the Operating Surgeon

- a. On a scale of 0 – 100 (100 being the **MOST**), how confident are you that this patient will have a satisfactory long-term result?
 - i. Post operative (within one hour of finishing): _____
- b. On a scale of 0 – 100 (100 being the **MOST**), how confident are you that this patient will have an uncomplicated post operative course?
 - i. Post operative (within one hour of finishing): _____
- c. Were you aware of any technical problems with this operation?
- d. Do you feel that there were any slips, errors or mistakes in the procedure?

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8.7 Appendix G – Hip Arthroscopy Theatre Preparation List

As discussed in *Chapter 6: Empirical Study II*, a scanned copy of the original *Hip Arthroscopy Theatre Preparation List (Preparation Checklist)* is presented below.

Note: identifying information has been covered to ensure the anonymity of the consultant surgeon.

Hip Arthroscopy Theatre preparation

- Sets and soft pack ready
- Spinal table into theatre
- Traction, see traction set up
- Stack – Plugged in correctly
 - Add and save patients for list
 - Set screens in right place for operation
 - Enter all details on surgeons screen, in right place
 - Foot pedals in right place
- Lights in correct place
- Surgeons screen in correct place (right or left)
- Saline 3000ml bags plenty, prepared in bucket of warm water
- Drip stand with bells ready
- Suction unit, plenty of liners ready
- Large bucket under table for suction tubing
- X-Ray machine in ready on correct side, called radiographer
- Check printer and paper ready
- Xylocaine 1.80,000 ready 1% with adrenaline 1:200,000.
- Marcain 0.5%
- ~~Cut padding and mefix ready~~ SURGIPADS + MEFIX IF REQUIRED
- Biogel 8.5 gloves
- Pink chlorhexadine prep

* ArthroCore machine

8.8 Appendix H – Hip Arthroscopy Specialist Equipment

As discussed in *Chapter 6: Empirical Study II*, photographs of the specialist equipment used in hip arthroscopy surgery are presented below.

8.8.1 Traction Table

The traction table is used to fix the patient's foot to the device. The patient's leg is pulled so that the surgeon can access the hip joint with surgical equipment.



Photograph 8.7.1-1: Traction Table.



Photograph 8.7.1-2: Traction table with patient's foot in a fixed position.

8.8.2 C-arm X-ray Machine

The C-arm X-ray machine is used to capture X-ray images of the patient's hip.



Photograph 8.7.2-1: C-arm X-ray machine.



Photograph 8.7.2-2: C-arm X-ray machine being moved into position over the traction table.



Photograph 8.7.2-3: C-arm X-ray machine with sterile covers in position over the traction table.

8.8.3 Stack System

The Stack System is used to control connected surgical equipment. This system is specific to hip arthroscopy surgery.



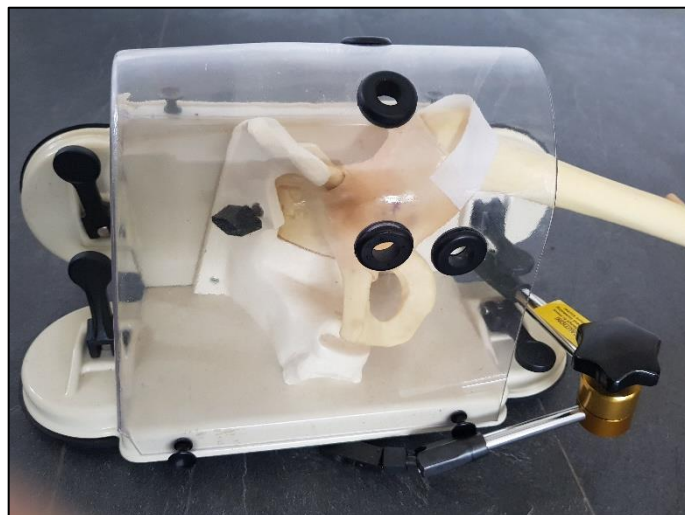
Photograph 8.7.3-1: Stack System positioned in the sterile field. The touch screen monitor is covered with a sterile cover.

8.9 Appendix I – Hip Model

As discussed in *Chapter 6: Empirical Study II*, photographs of the hip model used for scrub nurse familiarisation sessions are provided below.



Photograph 8.8-1: Hip model shown from the top view.



Photograph 8.8-2: Hip model shown from the side view.

8.10 Appendix J – Preparation Checklist Items

As discussed in *Chapter 6: Empirical Study II*, a tabular description of the *Preparation Checklist Items* represented as goals is provided below. Eighteen items are represented as goals and are described with associated information related to the actors and artefacts involved.

An in-depth analysis of each goal is provided in the form of a narrative. The narrative supports each goal by describing how knowledge is distributed within and between actors. Additional information is provided to describe the artefacts in their representational states and how artefacts are used, i.e. whether they are used in isolation or if interaction is required with other artefacts. Finally, opportunities for redesign are proposed with a limitation that the appropriateness and success of the redesign cannot be validated without further consideration, trial, and implementation.

8.10.1 Preparation Checklist: Item 1

Table 8-1: Preparation Checklist: Item 1 is provided below.

Table 8-1: Preparation Checklist: Item 1

Goal	Actors	Artefacts (representational state)
Sets and soft packs ready	Responsible: Scrub nurse Interactions with other Actors: External department personnel (sterile services) Instrument coordinator (non-clinical) Circulating nurse	Patient list for specialist equipment (stack system monitor – physical item + printed paper) Equipment order sheet (email and printed paper) Telephone (physical object) Equipment tray external label (printed paper stuck onto tray) Equipment tray internal list of contents (printed paper) Computer (physical object)

8.10.1.1 Goal

The goal 'sets and soft packs ready' refers to the surgical equipment required for hip arthroscopy surgery. 'Sets' refer to equipment sets which are pre-packed and sterilised in metal trays. Basic sets contain standard equipment. Other sets can contain specialised equipment determined by the complexity of the hip arthroscopy surgery. 'Soft packs' refer to other equipment contained in soft packaging, i.e. non-metal trays.

8.10.1.2 Distribution of knowledge

Multiple actors are required to achieve this goal. Firstly, knowledge is distributed externally to the operating theatre and secondly, internally to the operating theatre. Cognitive processes involve decision-making, external and internal communication and coordination, utilising various artefacts accessible within the operating theatre.

At least one day before surgery is scheduled, an order sheet must be completed and sent to the equipment preparation department. This department is responsible for ensuring that the ordered hip arthroscopy equipment sets are available and sterilised. On the morning of surgery, a telephone call is made to confirm the availability of the requested equipment sets and delivery to the relevant operating theatre. The equipment sets are delivered and left either outside of the operating theatre door or inside the equipment storage room within the operating theatre.

The scrub nurse is responsible for receiving the equipment sets of equipment in the operating theatre. The scrub nurse is responsible for checking the external labels of each tray against the printed order sheet. The scrub nurse coordinates with a circulating nurse to verbally cross check that the equipment sets are correct.

When unwrapped and opened, each tray contains a printed list of items contained within the tray. This printed list is only accessible once the tray has been opened. The scrub nurse retrieves the printed list and visually checks the contents of the tray. The printed list is then handed to the circulating nurse.

Access to information is spread across multiple representational states. The spread of information required to achieve this goal is both external to the operating theatre and internal within the operating theatre. Information is in paper form and physical form i.e. equipment. Additional information related to contents of the equipment trays is only accessible once the equipment trays have been received and opened.

8.10.1.3 Opportunity for redistribution of knowledge to new artefacts

Currently, multiple paper lists are used to check the contents of the equipment trays and other necessary equipment. This presents an opportunity to redistribute knowledge to the following new artefacts:

- a) a diagram detailing the layout and contents of the basic sets and specialist sets;
- b) a standard list related to soft packs required for each hip arthroscopy; and
- c) a challenge and response style protocol to verbally check and confirm contents of each equipment tray.

Both diagrams and lists could be placed on the operating theatre wall in the equipment preparation area for visible reference during completion of this goal. This has the potential to improve access to knowledge and shared information. A verbal protocol may assist in completion of this goal. Responsibility of the goal could be redistributed to a dedicated circulating nurse, who is made responsible for handover of the equipment to the scrub nurse.

8.10.2 Preparation Checklist: Item 2

Table 8-2: Preparation Checklist: Item 2 is provided below.

Table 8-2: Preparation Checklist: Item 2

Goal	Actors	Artefacts (representational state)
Spinal table into theatre	Responsible: Scrub nurse Interaction with other actors: Hospital porter Circulating nurses	Patient list (stack system monitor – physical item + printed paper)

8.10.2.1 Goal

The goal 'spinal table into theatre' refers to access and positioning of the traction table, which is specific to hip arthroscopy surgery. The table must be:

- available for use (it is typically located outside of the operating theatre as this is a specialist table and not used in other surgical specialties);
- positioned for the type of hip arthroscopy surgery; and
- positioned for the side of operation.

8.10.2.2 Distribution of knowledge

Multiple actors are required for this goal. Coordination between three theatre team members is required. Cognitive processes firstly involve a decision that the table is needed in the operating theatre. This decision was observed to be mostly implicit and the goal is initiated without verbal communication. On a small number of occasions when this goal was made explicit, communication and coordination were directed by the scrub nurse to the circulating nurse.

To manoeuvre the table requires at least two individuals; the hospital porter and a circulating nurse typically complete this task. When the traction table is wheeled into the operating theatre, there are no floor markers to determine where exactly it needs to be positioned. In the operating theatre under study, there were no sterile zone markers as observed in other operating theatres. Therefore, the positioning of the traction table appears to be known through experience.

Access to information is mostly via physical information related to whether the traction table is present or not in the operating theatre. This confirms if the goal is complete. No verbal communication was observed related to this goal.

8.10.2.3 Opportunity for redistribution of knowledge to new artefact

Distribution of knowledge in this goal is implicit and confirmed by physical presence of the traction table. Currently, no reference material is visible or known for positioning of the traction table in the operating theatre. This presents an opportunity to redistribute knowledge to the following new artefacts:

- a) a verbal protocol announcing that the operating theatre is ready for the traction table. For a full day of hip arthroscopies within the same operating theatre, this would only be necessary at the start of the day;
- b) a diagram for table positioning on the operating theatre wall;
- c) floor markers for table positioning; these can be temporary for when hip arthroscopy surgery is being conducted or permanent and applicable to all surgical specialties; and
- d) an end of day protocol to remove the traction table from the operating theatre.

8.10.3 Preparation Checklist: Item 3

Table 8-3: Preparation Checklist: Item 3 is provided below.

Table 8-3: Preparation Checklist: Item 3

Goal	Actors	Artefacts (representational state)
Traction, see traction set up	Responsible: Scrub nurse Interaction with other actors: Anaesthetic ODP practitioner Circulating nurse	Patient list (stack system monitor – physical item + printed paper)

8.10.3.1 Goal

The goal ‘traction’ refers to set-up of the traction machine which is part of the traction table. Setting the traction is performed manually. The required setting involves referencing the type of hip arthroscopy surgery specific to the patient position on the table, i.e. supine (lying flat on the back) or lateral (lying on either the left or right side). The traction machine is set at the appropriate length and angle to receive the patient’s foot for fixed positioning.

8.10.3.2 Distribution of knowledge:

At least one member of the theatre team is required to set the traction. The traction is often set by a circulating nurse. Cognitive processes observed involve no verbal callout to set the traction. Setting the traction machine appears to be implicitly known through experience and performed by an experienced theatre team member. On completion of this goal, no verbal or physical check was observed. However, this may have been confirmed implicitly while positioning the patient. Access to information is possibly a visual check when the traction machine is set.

8.10.3.3 Opportunity for redistribution of knowledge to new artefacts

Distribution of knowledge in this goal is implicit and confirmed by physical setting of the traction machine. Currently, no reference material is visible or known for setting the traction machine in the correct position for the patient's requirements. This presents an opportunity to redistribute knowledge to the following new artefacts:

- a) a diagram showing the correct setting for supine and lateral positioning could be present on the operating theatre wall. This would need to be in close proximity to the traction machine; and
- b) a verbal protocol could be designed for use between the scrub nurse and the circulating nurse to:
 - i. check the traction setting requirements against the patient list;
 - ii. confirm when the traction is set by the circulating nurse; and
 - iii. cross-check the traction setting by the scrub nurse.

8.10.4 Preparation Checklist: Item 4

Table 8-4: Preparation Checklist: Item 4 is provided below.

Table 8-4: Preparation Checklist: Item 4

Goal	Actors	Artefacts (representational state)
Stack – plugged in correctly - Add and save patients for list - Set screens in right place for operation - Enter all details on surgeon's screen, in right place - Foot pedals in right place	Responsible: Scrub nurse Interaction with other actors: Circulating nurse	Stack system labels (physical object with information printed onto the machine) Stack system plug holes (physical object) Stack system feedback - switches on/off and lights on/off. (physical object) Patient list (stack system monitor – physical item + printed paper) Surgeon's monitor (physical object) Foot pedal shapes and labels (physical object)

8.10.4.1 Goal

The goal 'stack' refers to the stack system, which is crucial to the correct functioning of various individual pieces of equipment that plug into the stack system. This goal refers to multiple aspects related to preparation, including:

- positioning of the stack machine within close proximity to the sterile operating field; and
- set-up of the machine.

The stack system consists of separate units, each of which drives multiple pieces of equipment. If any connection is set incorrectly, this results in a delay to the surgical process flow whilst the error is identified and reconnected. Embedded in this goal are four sub-goals, two of which are not related to the stack system.

8.10.4.1.1 Sub-goal 1: 'Add and save patients for list'

The patient list is printed from a computer on A4 paper. This information is manually transferred to the stack system. This information is displayed on the stack system monitor. The scrub nurse can select the patient from the monitor touch screen to prepare the operating theatre for their surgical specific requirements.

8.10.4.1.2 Sub-goal 2: 'Set screens in right place for operation'

This refers to positioning of the surgeon's monitor in the appropriate position relative to the patient's operation side and where the consultant surgeon will stand to perform the surgery.

8.10.4.1.3 Sub-goal 3: 'Enter all details on surgeons screen, in right place'

Patient information such as X-rays are entered into the computer and displayed on the surgeon's monitor for reference by the consultant surgeon.

8.10.4.1.4 Sub-goal 4: 'Foot pedals in right place'

Up to three sets of foot pedals can be positioned on the floor at the consultant surgeon's station. All foot pedals need to be correctly plugged into the stack system. Each foot pedal operates a different piece of equipment e.g. shaver. The location of the foot pedals is essential for the following reasons:

- a) the pedals are often positioned underneath the operating table and the table sterile drape hinders visible access; and
- b) the order in which the pedals are positioned is essential for the consultant surgeon to know which pedal to operate by feeling the shape

with their foot. For example, the left pedal operates the radio frequency and the right pedal operates the shaver.

Pedals are shaped differently to indicate left foot or right foot positioning. It is extremely difficult for the surgeon to visually see the pedals as their position underneath the drapes requires them to be located by searching with the foot.

8.10.4.2 Distribution of knowledge

For the overall goal 'stack – plugged in correctly', multiple actors are required for this goal. Coordination between the scrub nurse and at least one circulating nurse is required. Cognitive processes involve the correct connection of multiple cables. Each cable must be connected to the relevant slot within the stack system individual machines. A decision must be made to start connecting cables to the stack system; this was observed to be implicit as no verbal callout was made to initiate this process. There does not appear to be a systematic method for setting up the stack system. The order in which the equipment is connected is varied, and no verbal confirmation for correct set-up was observed.

The distribution of knowledge is complex. Information is neither obvious nor consistent. The scrub nurse is scrubbed and positioned in the sterile zone. The circulating nurse or the scrub nurse performs this task from memory. No visual check or verbal confirmation was observed. No confirmation cross-checks were observed. Access to information is via labelling of each section of the stack system and a colour coded cable with matching receiver port. The name of equipment corresponds to the label on the machine section within the stack system. Colour coded cables assist with connecting the right cable to the machine in the stack and then to the right slot. Switch position indicates on or off. When correctly connected, feedback is received from the light next to the connector.

A stack system manual is available; it is produced by the stack system manufacturer. This is available in the operating theatre for reference but is not referred to unless an issue occurs with malfunctioning equipment. Theatre

team members were observed to know how to set up the stack system by experience.

8.10.4.2.1 Sub-goal 1: 'Add and save patients for list'; Distribution of knowledge

At least one actor is required for completion of this goal. Patient data is transferred from the printed patient list to the computer to be displayed on the surgeon's monitor. Cognitive processes involve a decision to print the patient list so that this is available in the operating theatre. The scrub nurse or a circulating nurse takes responsibility for transferring the patient data from the printed patient list to the computer. No verbal communication was observed, and this goal appears to be performed implicitly. Access to information is possible from the printed patient list and feedback from the monitor where the patient information is displayed.

8.10.4.2.2 Sub-goal 2: 'Set screens in right place for operation'; Distribution of knowledge

One theatre team member is required to complete this goal. Typically, the scrub nurse performs this goal in isolation because the monitor is positioned within the sterile field and more easily accessed by the scrub nurse. Cognitive processes involve a decision to position the surgeons monitor. One person must reach to access the monitor, then cross check the position with the patient list to identify which side the next patient will be positioned. Access to information is via the monitor position as physical information. The position of the traction table and equipment set-up confirms the side of patient's operation and where the consultant surgeon will stand. There is no additional information available to check the correct position of the monitor, i.e. the height of the monitor in relation to the surgeon's height until the surgeon is present in the sterile field and confirms the correct position.

8.10.4.2.3 Sub-goal 3: 'Enter all details on surgeons screen, in right place'; Distribution of knowledge

The scrub nurse or a circulating nurse takes responsibility for this goal. One member for the theatre team performs this goal. Cognitive processes involve a decision to enter all required details. Accurate data entry is required from the printed paper to the computer. Access to information is via the printed paper and information is visibly displayed on the monitor screen as feedback from entered data.

8.10.4.2.4 Sub-goal 4: 'Foot pedals in right place'; Distribution of knowledge

Two members of the theatre team are required for this goal; coordination between the scrub nurse and a circulating nurse is required. The foot pedals are collected from the equipment storage room, they are connected to the stack machine and positioned on the floor at the appropriate position for the consultant surgeon. Cognitive processes involve a decision to retrieve the foot pedals, coordination to position the pedals and each pedal is connected. Access to information is via visual information regarding whether the pedals are available and correctly positioned.

8.10.4.2.5 Opportunity for redistribution of knowledge to new artefacts

Distribution of knowledge in this goal is implicit. This presents an opportunity to redistribute knowledge to the following new artefact:

- a) a specific checklist for stack system set-up could be designed with specific references to each individual cable to be attached to the stack system sections. This could be a 'challenge and response style' checklist whereby 2 actors are involved in the process: one performing the action and one visually checking the correct action and then verbally confirming.

Note: at the time of data collection, the stack system was used as a visual reference with visual feedback. At the time of data validation with the

scrub nurse, the stack system had been upgraded to a new system. Feedback is now given audibly from this new system. There is also a default setting on the new stack system whereby the settings for each consultant can be saved and recalled when required.

8.10.5 Preparation Checklist: Item 5

Table 8-5: Preparation Checklist: Item 5 is provided below.

Table 8-5: Preparation Checklist: Item 5

Goal	Actors	Artefacts (representational state)
Lights in correct place	Responsible: Scrub nurse Interaction with other actors: Surgeon Assisting surgeon Circulating	Equipment box label (printed paper stuck onto box) Sterile handle packaging label (printed onto packaging)

8.10.5.1 Goal

The goal 'lights' refers to positioning of the lights over the surgical field. Operating theatre lights are lowered during surgery and overhead lights are required for the surgeon to see the operating site. Spotlights are positioned overhead within the sterile zone on a swing arm attached to the ceiling. Sterile hand-grip covers are required for manoeuvring the spotlights when in use during surgery. These are handed to the scrub nurse by a circulating nurse during preparation of the operating theatre. Spotlights are manually positioned by manoeuvring the swing arm and positioning the lights in the required location.

8.10.5.2 Distribution of knowledge

Two actors are required for completion of this goal. Coordination between the scrub nurse and a circulating nurse is required. Cognitive processes involve a decision to prepare the lights, a decision to access the sterilised light handles from the equipment storage room, and the light handles are correctly

positioned. Access to information is via visual information of whether the lights are in position. In addition, physical information is available to confirm if the light handles are in place. There is no light set-up confirmation. The scrub nurse places the overhead spotlights over the operating table. The consultant surgeon often manoeuvres the lights into a new position at the start of the operation.

8.10.5.3 Opportunity for redistribution of knowledge to new artefacts

Distribution of knowledge in this goal is implicit and confirmed by physical confirmation. Currently, no reference material is visible or known for setting the overhead lights in the correct position for the surgeon. This presents an opportunity to redistribute knowledge to the following new artefacts:

- a) a diagram detailing ideal positioning of the lights over the patient's traction table could be placed on the operating theatre wall for reference; and
- b) a verbal protocol between the scrub nurse and the consultant surgeon prior to surgery commencing to confirm that the light handles are in place and the overhead lights are in the correct position. This may be followed by a physical check on a checklist, which could be completed by a circulating nurse.

8.10.6 Preparation Checklist: Item 6

Table 8-6: Preparation Checklist: Item 6 is provided below.

Table 8-6: Preparation Checklist: Item 6

Goal	Actors	Artefacts (representational state)
Surgeon's screen in correct place (right or left)	Responsible: Scrub nurse Interaction with other actors: Circulating nurse	Patient list (stack system monitor – physical item + printed paper) Surgeon's monitor (physical object)

8.10.6.1 Goal

The goal 'surgeon's screen' refers to positioning of the monitor which displays a visual image of the inside of the patient's hip from the scope. The scope is inserted into the hip joint and manually manoeuvred by the consultant surgeon to view different parts of the hip.

8.10.6.2 Distribution of knowledge

One actor is required for completion of this goal. Typically, the scrub nurse positions this monitor screen within the sterile field. Cognitive processes involve decision-making to know when to prepare the position of the monitor. Access to information is via the physical position of the monitor, which represents action and completion of the goal. However, the surgeon will often reposition the monitor once present in the sterile field.

8.10.6.3 Opportunity for redistribution of knowledge to new artefacts

Distribution of knowledge in this goal is implicit and confirmed by physical confirmation. Currently, no reference material is visible or known for setting

the surgeon's monitor in the correct position for the surgeon. This presents an opportunity to redistribute knowledge to the following new artefacts:

- a) a diagram detailing ideal positioning relative to the consultant surgeon could be placed on the operating theatre wall for reference; and
- b) a verbal protocol between the scrub nurse and the consultant surgeon prior to surgery commencing to confirm correct position. This could be followed by a physical check mark on the preparation checklist to be completed by a circulating nurse outside of the sterile zone.

8.10.7 Preparation Checklist: Item 7

Table 8-7: Preparation Checklist: Item 7 is provided below.

Table 8-7: Preparation Checklist: Item 7

Goal	Actors	Artefacts (representational state)
Saline 3 bags plenty, prepared in a bucket of warm water	Responsible: Scrub nurse Interaction with other actors: Circulating nurse	Saline bag labels (printed onto saline bag) Bucket (physical object)

8.10.7.1 Goal

The goal related to 'saline' refers to access to extra saline bags within the surgical field. Availability of saline bags is important for continued surgical flow.

8.10.7.2 Distribution of knowledge

Multiple actors are required to achieve this goal. Communication and coordination between the scrub nurse and circulating nurse is required. Cognitive processes involve a decision to prepare adequate saline bags within access to the sterile field. Access to information is via the physical presence of the saline bags which provide a visual reference.

8.10.7.3 Opportunity for redistribution of knowledge to new artefacts

Distribution of knowledge in this goal is implicit and confirmed by physical confirmation. This presents an opportunity to redistribute knowledge within the current artefact: the preparation checklist could contain a two-stage check:

one to physically check the available saline bags and one for verbal confirmation of their position.

Note: This represents the old method which was reliant on theatre team members. Since data collection, a new system is legally required. The new system is an advanced automatic fluid warmer. The automatic warmer represents an advancement in technology and a transfer of knowledge from the human to technology.

8.10.8 Preparation Checklist: Item 8

Table 8-8: Preparation Checklist: Item 8 is provided below.

Table 8-8: Preparation Checklist: Item 8

Goal	Actors	Artefacts (representational state)
Drip stand with bells ready	Responsible: Scrub nurse Interaction with other actors: Circulating nurse	Bell switch position (physical object)

8.10.8.1 Goal

The goal related to the ‘drip stand’ refers to positioning of the drip stand within the surgical field and set-up, i.e. the bells are required to alert the theatre team of low saline solution, at which point the bag must be changed.

8.10.8.2 Distribution of knowledge

Multiple actors are required to achieve this goal. Communication and coordination between the scrub nurse and circulating nurse is required. Cognitive processes involve decision-making to firstly know that the saline bag is low, and secondly, at which point to replace it with a full saline bag. Access to information is via visual feedback and audio feedback to alert the theatre team if a saline bag requires replacement. The saline bag is clear, and confirming the liquid level provides a visual reference. This mode of information requires attention from at least one theatre team member. In addition, the saline bag has a warning bell to alert the theatre team that the saline levels are low.

8.10.8.3 Opportunity for redistribution of knowledge to new artefacts

Distribution of knowledge in this goal is implicit and confirmed by physical confirmation. This presents an opportunity to redistribute knowledge within the current artefact: the preparation checklist could contain a two-stage check: one to physically check the available saline bags and one for verbal confirmation of the level.

Note: at the time of data collection, the system was manufactured by one company. At the time of data validation, the system had been changed to one manufactured by a different company. The automatic warmer represents an advancement in technology and a transfer of knowledge from the human to technology.

8.10.9 Preparation Checklist: Item 9

Table 8-9: Preparation Checklist: Item 9 is provided below.

Table 8-9: Preparation Checklist: Item 9

Goal	Actors	Artefacts (representational state)
Suction unit, plenty of liners ready	Responsible: Scrub nurse Interaction with other actors: Circulating nurse	Suction canister (physical object)

8.10.9.1 Goal

The goal related to the 'suction unit' refers to positioning and set-up. Set-up requires the suction unit to be in position and a liner in place. A check is then made to confirm that the suction is working correctly.

8.10.9.2 Distribution of knowledge

Multiple actors are required for this goal. Coordination between the scrub nurse and circulating nurse is required. Cognitive processes involve a decision to place a liner inside the canister and a visual check of the canister to confirm if it is working correctly. Access to information is via visual confirmation of the liner present inside the canister.

8.10.9.3 Opportunity for redistribution of knowledge to new artefacts

Distribution of knowledge in this goal is implicit and confirmed by physical confirmation. This presents an opportunity to redistribute knowledge within the current artefact: the preparation checklist could contain a two-stage check:

one to physically check the liner is inside the canister and one for verbal confirmation.

8.10.10 Preparation Checklist: Item 10

Table 8-10: Preparation Checklist: Item 10 is provided below.

Table 8-10: Preparation Checklist: Item 10

Goal	Actors	Artefacts (representational state)
Large Bucket under table for suction tubing	<p>Responsible:</p> <p>Scrub nurse</p> <p>Interaction with other actors:</p> <p>Circulating nurse</p>	Bucket (physical object)

8.10.10.1 Goal

The goal related to a 'large bucket' refers to positioning of a bucket underneath the operating table whereby the suction tube is placed to collect fluids.

8.10.10.2 Distribution of knowledge

Multiple actors are required for this goal. Coordination and communication between the scrub nurse and a circulating nurse is required. Cognitive processes involve deciding to retrieve the bucket from the equipment storage room and place it in the correct position. Access to information is via a visual reference of the bucket in the correct position.

8.10.10.3 Opportunity for redistribution of knowledge to new artefacts

Distribution of knowledge in this goal is implicit and confirmed by physical confirmation. This presents an opportunity to redistribute knowledge within the

current artefact: the preparation checklist could contain a two-stage check: one to physically check the canister and one for verbal confirmation.

8.10.11 Preparation Checklist: Item 11

Table 8-11: Preparation Checklist: Item 11 is provided below.

Table 8-11: Preparation Checklist: Item 11

Goal	Actors	Artefacts (representational state)
X-ray machine in ready on correct side, called radiographer	<p>Responsible:</p> <p>Scrub nurse</p> <p>Interaction with other actors:</p> <p>Radiographer</p> <p>Circulating nurse</p>	<p>Telephone (physical object)</p> <p>Patient list (stack system monitor – physical item + printed paper)</p> <p>C-arm switch - on position (physical object)</p> <p>C-arm lights - feedback to confirm ready (physical object)</p>

8.10.11.1 Goal

The goal related to 'X-ray machine' refers to the following steps related to the C-arm X-ray machine:

- C-arm X-ray is available in the operating theatre;
- positioning of the C-arm in the correct location related to the patient's side of operation;
- a radiographer is available to operate the C-arm; and
- the C-arm is checked to ensure that it is in working order ready for use in surgery.

8.10.11.2 Distribution of knowledge

Multiple actors are required for this goal. Multiple interactions are required, both externally to the operating theatre and internally within the operating theatre. The scrub nurse is responsible for this goal and must coordinate with the radiology department ahead of surgery. The C-arm is transported from the radiology department to the operating theatre. The scrub nurse makes a telephone call to the radiology department prior to scrubbing for surgery. This is to ensure a radiologist is available to operate the C-arm X-ray machine. Cognitive processes are complex and require multiple decisions and multiple stages of coordination; these stages require interaction with several artefacts. Initiation of the event requires the scrub nurse to decide if the operating theatre is ready to receive the C-arm. The scrub nurse or circulating nurse makes a phone telephone call to the radiology department for a radiographer to arrive at the operating theatre to operate the C-arm. Access to information involves the C-arm physically present in the operating theatre. After the telephone call, the next access to information is arrival of the radiographer in the operating theatre. If no radiographer arrives, there is no other form of intermediate access to information available without another telephone call to the radiography department.

8.10.11.3 Opportunity for redistribution of knowledge to new artefacts

Distribution of knowledge in this goal is implicit and confirmed by physical confirmation. This presents an opportunity to redistribute knowledge to a new artefact:

- a) a verbal protocol could confirm arrival of the C-arm X-ray machine into the operating theatre. This would contain a three-stage check: one to announce the arrival of the C-arm X-ray, one to physically check the presence of the C-arm X-ray, and one for verbal confirmation of the C-arm X-ray in the operating theatre prior to surgery; and
- b) a verbal protocol to confirm arrival of the radiographer into the operating theatre. This would contain a three-stage check: one to announce the arrival of the radiographer, one to physically check the

presence of the radiographer, and one for verbal confirmation that the radiographer is present in the operating theatre prior to surgery.

8.10.12 Preparation Checklist: Item 12

Table 8-12: Preparation Checklist: Item 12 is provided below.

Table 8-12: Preparation Checklist: Item 12

Goal	Actors	Artefacts (representational state)
Check printer and paper ready	<p>Responsible:</p> <p>Scrub nurse</p> <p>Interaction with other actors:</p> <p>Circulating nurse</p>	<p>Printer switch - on position (physical object)</p> <p>Printer light - confirm ready to print (physical object)</p> <p>Paper (physical object)</p>

8.10.12.1 Goal

The goal related to the 'printer' refers to set-up of the printer ready for use during surgery. The printer must be switched on with A4 paper loaded. A test sheet must be printed to ensure that the printer is ready for use. The printer is used to print screen captures of the patient's hip on the direction of the consultant surgeon. The screen captures are placed in the patient's medical file for post-surgery reference.

8.10.12.2 Distribution of knowledge

Multiple actors are required for this goal. Coordination and communication between the scrub nurse and the circulating nurse is required. Cognitive processes involve a decision to load the printer with paper, a decision to action a test sheet, and a decision to action the availability of additional paper. Access to information is via multiple visual checks. Visual information is

available from the printer when no paper is available. A light indication flashes on the printer when the ribbon ink is at the end.

8.10.12.3 Opportunity for redistribution of knowledge to new artefacts

Distribution of knowledge in this goal is implicit and confirmed by physical confirmation. This presents an opportunity to redistribute knowledge to a new artefact: a verbal protocol could confirm that the printer is set and ready for surgery. This would contain a three-stage check: one to confirm that the printer is on, one to physically check the paper is loaded into the printer, and one to verbally confirm when a test page had been printed successfully.

8.10.13 Preparation Checklist: Item 13

Table 8-13: Preparation Checklist: Item 13 is provided below.

Table 8-13: Preparation Checklist: Item 13

Goal	Actors	Artefacts (representational state)
Xylocaine 1% with adrenaline 1:200,000	Responsible: Scrub nurse Interaction with other actors: Anaesthetist Circulating nurse	Solution bottle label (printed paper stuck on bottle) Patient list to check for allergies (stack system monitor – physical item + printed paper) Syringe and needle packaging (physical object with printed information on packaging)

8.10.13.1 Goal

The goal related to 'Xylocaine' refers to access to the solution with adrenaline. The anaesthetists must check the solution label, and the circulating nurse holds the bottle whilst the scrub nurse draws the solution into a syringe and rests the prepared solution in a bowl on one of the equipment tables.

8.10.13.2 Distribution of knowledge

Multiple actors are required to achieve this goal. Knowledge is distributed through communication and coordination between the actors. One main artefact is involved, i.e. the solution label printed on the bottle. Cognitive processes involve a verbal handover of the solution from the anaesthetist, a read-out of the label by the circulating nurse to the scrub nurse, followed by

visual confirmation of information of the solution label. The scrub nurse, circulating nurse, and anaesthetist all interact verbally. Access to information is via verbal statements and visually confirming the information on the solution labels.

8.10.13.3 Opportunity for redistribution of knowledge to new artefacts

Distribution of knowledge in this goal is explicit and confirmed by verbal and visual checks. However, a further opportunity to redistribute knowledge to a new artefact is presented: a verbal protocol could be standardised to confirm the solution. This would contain a two-stage check: one to confirm the solution handover between the anaesthetist and the circulating nurse, and one to confirm the solution handover between the circulating nurse and the scrub nurse.

8.10.14 Preparation Checklist: Item 14

Table 8-14: Preparation Checklist: Item 14 is provided below.

Table 8-14: Preparation Checklist: Item 14

Goal	Actors	Artefacts (representational state)
Marcain 0.5%	Responsible: Scrub nurse Interaction with other actors: Anaesthetist Circulating nurse	Solution bottle label (printed paper stuck on bottle) Patient list to check for allergies (stack system monitor – physical item + printed paper) Syringe and needle packaging (physical object with printed information on packaging)

8.10.14.1 Goal

The goal related to 'Marcain' refers to access to the local anaesthesia to be injected into the patient. The anaesthetists must check the solution label, and the circulating nurse holds the bottle whilst the scrub nurse draws the solution into a syringe and rests the prepared solution in a bowl on one of the equipment tables.

8.10.14.2 Distribution of knowledge

Multiple actors are required to achieve this goal. Knowledge is distributed through communication and coordination between the actors. Two main artefacts are involved: one is the printed patient list to confirm allergies, another is the solution label printed on the bottle. Cognitive processes involve

decision-making, communication and coordination utilising various artefacts. The anaesthetist conducts a verbal handover of the solution to the circulating nurse, who then verbally reads the label information to the scrub nurse. This is followed by a visual confirmation of information of the solution label. The scrub nurse, circulating nurse, and anaesthetist all interact verbally. Access to information is via verbal statements and visually confirming the information on the solution labels. The solution bottle is shown to the scrub nurse. The scrub nurse verbally reads aloud the name on the solution label. After confirmation of the solution, the scrub nurse draws the fluid into a syringe and places the syringe in a sterile bowl on the equipment table.

8.10.14.3 Opportunity for redistribution of knowledge to new artefacts

Distribution of knowledge in this goal is explicit and confirmed by verbal and visual checks. However, a further opportunity to redistribute knowledge to a new artefact is presented: a verbal protocol could be designed to standardise preparation to confirm the solution. This would contain a two-stage check: one to confirm the solution handover between the anaesthetist and the circulating nurse, and one to confirm the solution handover between the circulating nurse and the scrub nurse.

8.10.15 Preparation Checklist: Item 15

Table 8-15: Preparation Checklist: Item 15 is provided below.

Table 8-15: Preparation Checklist: Item 15

Goal	Actors	Artefacts (representational state)
Surgipads + Mefix if required	Responsible: Scrub nurse Interaction with other actors: Circulating nurse	Equipment storage boxes – external label (printed and stuck on box) Packaging labels (printed on packaging)

8.10.15.1 Goal

The goal related to ‘surgipads’ refers to access to surgical dressing. The additional goal for ‘Mefix’ is added to this item, which refers to adhesive fabric dressing to secure the surgical dressing in place on the patient’s wound.

8.10.15.2 Distribution of knowledge

Multiple actors are required to achieve this goal. Communication and coordination between the scrub nurse and the circulating nurse is required utilising various artefacts. Cognitive processes involve decision-making. Access to information is via the printed equipment box labels and the printed information on each physical object.

8.10.15.3 Opportunity for redistribution of knowledge to new artefacts

Distribution of knowledge in this goal is implicit and confirmed by a visual check. This presents an opportunity to redistribute knowledge to a new artefact: a verbal protocol could be designed to standardise preparation. This would contain a two-stage check: one to confirm the availability of the items

between the circulating nurse and the scrub nurse, and one to confirm that the items are in place on the equipment table.

Note: At the time of data collection, this process was accurate. At the time of data validation, the scrub nurse confirmed a new process whereby compression dressings are no longer used. Aquacel is used instead of Mefix as it is more absorbent.

8.10.16 Preparation Checklist: Item 16

Table 8-16: Preparation Checklist: Item 16 is provided below.

Table 8-16: Preparation Checklist: Item 16

Goal	Actors	Artefacts (representational state)
Biogel 8.5 gloves	Responsible: Scrub nurse Interaction with other actors: Circulating nurse	Equipment storage boxes – external label (printed paper stuck on box) Glove packaging label (printed on packaging) Gloves: size and position printed on glove. 'L' for left / 'R' for right. (physical object)

8.10.16.1 Goal

The goal related to 'Biogel gloves' refers to access to the correct type and size of operating gloves for the consultant surgeon.

8.10.16.2 Distribution of knowledge

Multiple actors are required to achieve this goal. Communication and coordination between the scrub nurse and the circulating nurse is required utilising various artefacts. Cognitive processes involve decision-making. Access to information is via the printed equipment box labels and the printed information on the glove packaging.

8.10.16.3 Opportunity for redistribution of knowledge to new artefacts

Distribution of knowledge in this goal is implicit and confirmed by a visual check. This presents an opportunity to redistribute knowledge to a new

artefact: a verbal protocol could be designed to standardise preparation. This would contain a two-stage check: one to confirm the availability of the gloves between the circulating nurse and the scrub nurse, and one to confirm that the gloves are in place for the consultant surgeon.

8.10.17 Preparation Checklist: Item 17

Table 8-17: Preparation Checklist: Item 17 is provided below.

Table 8-17: Preparation Checklist: Item 17

Goal	Actors	Artefacts (representational state)
Pink chlorhexidine prep	Responsible: Scrub nurse Interaction with other actors: Circulating nurse	Solution bottle label (printed paper stuck on the bottle) Patient list to check for allergies (stack system monitor – physical item + printed paper)

8.10.17.1 Goal

The goal related to 'chlorhexidine' refers to access to the preferred type of sterilising preparation fluid used for skin disinfection before surgery.

8.10.17.2 Distribution of knowledge

Multiple actors are required to achieve this goal. Communication and coordination between the scrub nurse and the circulating nurse is required utilising various artefacts. Cognitive processes involve decision-making. Access to information is via the printed equipment box labels and the printed information on the solution bottle.

8.10.17.3 Opportunity for redistribution of knowledge to new artefacts

Distribution of knowledge in this goal is implicit and confirmed by a visual check. This presents an opportunity to redistribute knowledge to a new artefact: a verbal protocol could be designed to standardise preparation. This would contain a two-stage check: one to confirm the availability of the solution

between the circulating nurse and the scrub nurse, and one to confirm that the solution is in place for on the equipment table.

8.10.18 Preparation Checklist: Item 18

Table 8-18: Preparation Checklist: Item 18 is provided below.

Table 8-18: Preparation Checklist: Item 18

Goal	Actors	Artefacts (representational state)
Arthrocare machine	Responsible: Scrub nurse Interaction with other actors: Circulating nurse	Machine information screen (physical object) Machine switch positions (physical object) Machine lights feedback (physical object) Instructions for use - if required (printed instruction booklet) Manual - if required (printed manual)

8.10.18.1 Goal

The goal 'Arthrocare machine' refers to positioning and set-up of the machine. The point on the preparation checklist acts as a trigger for preparation. The Arthrocare contains a radiofrequency wand used for a specific procedure within hip arthroscopy surgery. This machine is not routinely used. Operation of the machine is via a foot pedal containing two coloured pedals (left: yellow for 'ablate' / right: blue for 'coag').

8.10.18.2 Distribution of knowledge

Multiple actors are required to achieve this goal. Communication and coordination between the scrub nurse and the circulating nurse is required, utilising various artefacts. Cognitive processes involve decision-making.

Access to information is via verbal confirmation from the scrub nurse that the Arthrocare machine is required.

8.10.18.3 Opportunity for redistribution of knowledge to new artefacts

Distribution of knowledge in this goal is explicit and confirmed by a visual check. This presents an opportunity to redistribute knowledge to a new artefact: a verbal protocol could be designed to standardise preparation. This would contain a two-stage check: one to confirm the requirement of the Arthrocare machine between the circulating nurse and the scrub nurse, and one to confirm the Arthrocare machine is correctly set-up and in position relative to the surgeons' station.

Note: At the time of data collection, this process was accurate. At the time of data validation, a new system manufactured by another company and a new process was in place. This is supported by a new hospital policy and NICE guidelines.

8.11 Appendix K – Operating Theatre Artefacts

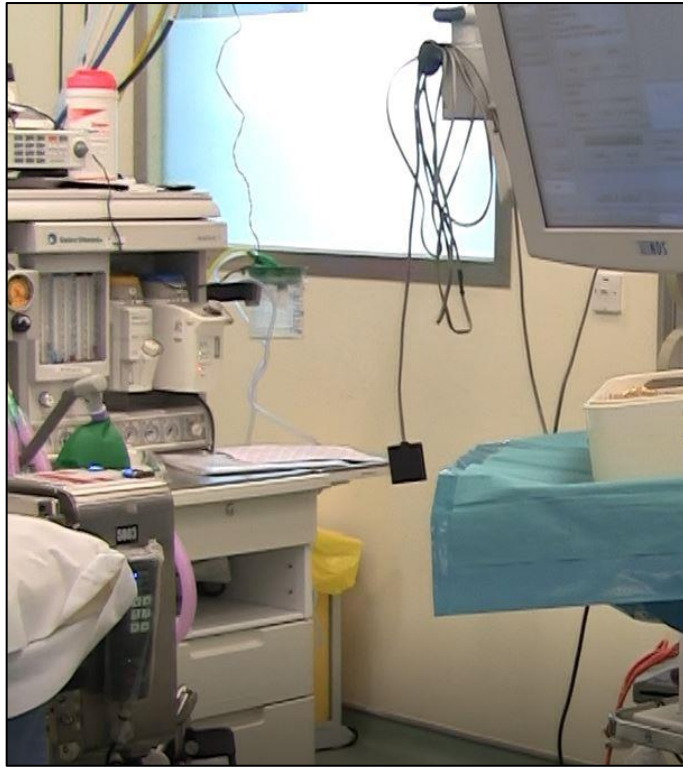
This appendix presents photographs of the artefacts referred to in *Chapter 6: Empirical Study II*. The photographs were captured during the observation of hip arthroscopy surgeries. They were taken using a *University of Warwick* owned camera, with permission from the lead consultant surgeon. No identifying information is contained within these photographs; they are presented to provide a visual of the artefacts discussed. As discussed in *Chapter 6: Empirical Study II*, photographs of the artefacts are provided below.

8.11.1 Operating Theatre White Boards

The operating theatre contains various white boards used by theatre team members to record information by handwritten notes. This information is accessible to all theatre team members and can be modified as required. Occasionally, the printed patient list is attached to this board using a magnet.



Photograph 8.10.1-1: Operating Theatre White Board



Photograph 8.10.1-2: Operating Theatre White Board

8.11.2 Printed Patient List

An operating theatre white board is used by theatre team members to display a printed patient list. This information is accessible by all theatre team members. A detailed copy of the patient list is not provided as it contains confidential data. However, an illustration is provided below.



Photograph 8.10-2-1: Printed Patient List on White Board

8.11.3 Operating Theatre Lights

Operating theatre lights require a sterile hand cover. The operating theatre lights are used by members of the theatre team positioned inside of the sterile field to manoeuvre the lights over the operating table, as required.



Photograph 8.10.3-1: Operating Theatre Lights

8.11.4 Operating Theatre Clock

Operating theatre timings were recorded using the operating theatre clock. Observers recorded performance timings from the same clock.



Photograph 8.10.4-1: Operating Theatre Clock

8.11.5 Surgical Equipment Trolleys

Surgical equipment trolleys with sterile equipment are stored in the operating theatre equipment storage room.



Photograph 8.10.5-1: Surgical Equipment Trolleys in Storage Room

8.11.6 Surgical Equipment Trays and Labels

Surgical equipment is stored in the operating theatre equipment storage room. Printed labels are stuck to the wrapping with additional handwritten notes.



Photograph 8.10.6-1: Surgical Equipment Trays and Labels

Sterile surgical equipment is stored in trays with a printed list of the sterile surgical equipment inside the tray.



Photograph 8.10.6-2: Sterile Surgical Equipment Tray and Printed List

8.11.7 Surgical Equipment Boxes and Labels

Surgical equipment is stored in the operating theatre equipment storage room in boxes with printed labels detailing the contents in each box.



Photograph 8.10.7-1: Surgical Equipment Boxes with Printed Labels



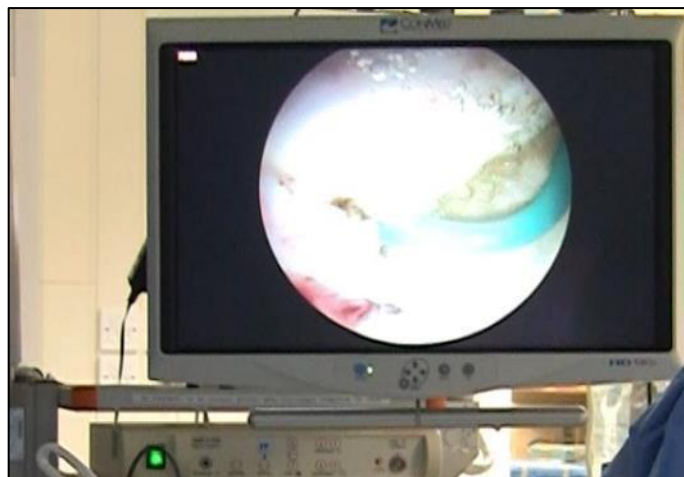
Photograph 8.10.7-2: Surgical Equipment Boxes with Printed Labels

8.11.8 Information Monitor Screens

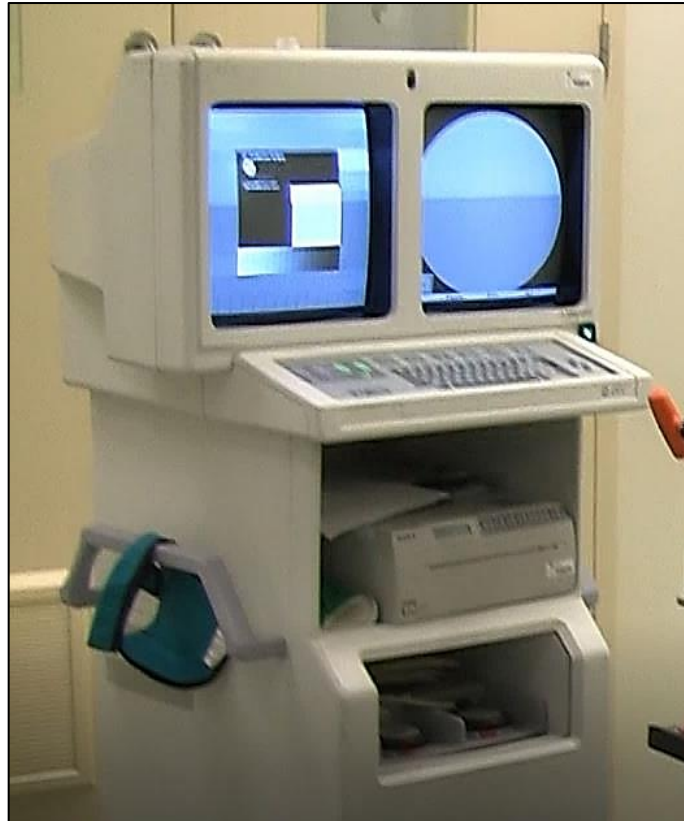
Various information monitors are used in the operating theatre for patient information and for use by the surgeon(s). A stack system can be used for the monitor screens. A touch screen is used by the scrub nurse to access patient information. A sterile cover is used to protect the scrub nurse from desterilisation.



Photograph 8.10.8-1: Stack System Monitor and Sterile Cover



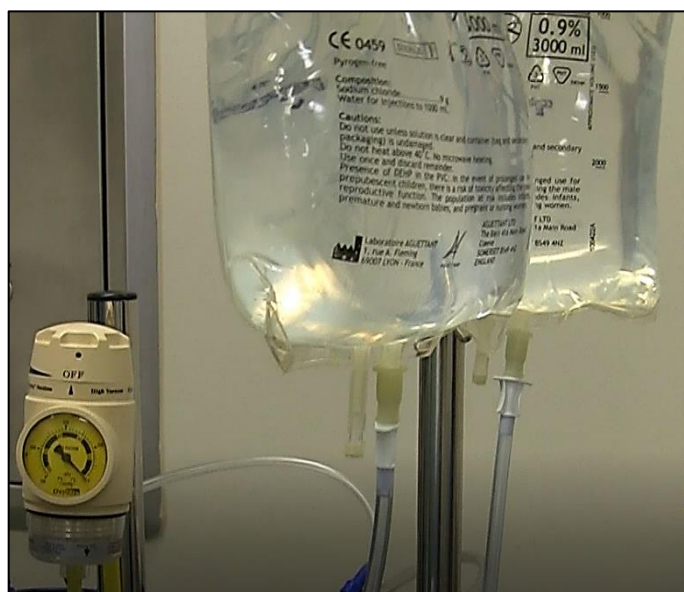
Photograph 8.10.8-3: Surgeon's Scope View Monitor



Photograph 8.10.8-4: X-Ray Monitor Screens

8.11.9 Saline Bags

Saline bags used in the operating theatre include printed information on the bag.



Photograph 8.10.9-1: Saline Bag with Printed Information

8.11.10 Solution Labels

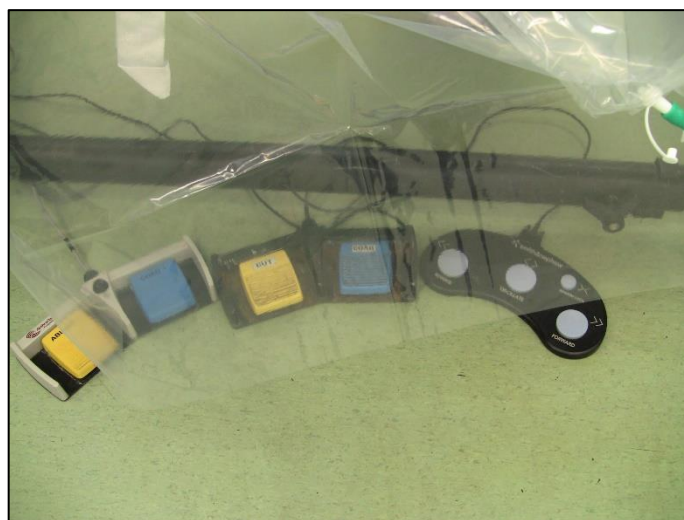
Solutions used in the operating theatre include printed information labels on the bottles.



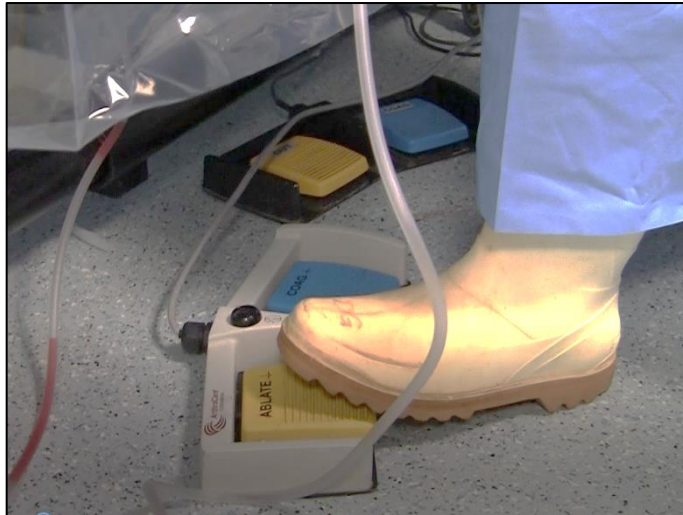
Photograph 8.10.10-1: Solution Bottles with Printed Information

8.11.11 Foot Pedals Positioning

Foot pedals to assist with operation of surgical equipment are positioned under the operating table.



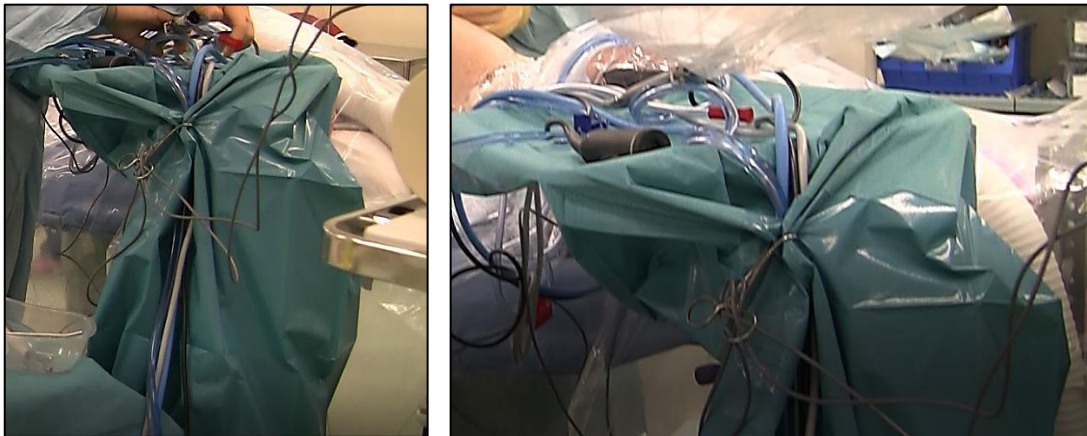
Photograph 8.10.11-1: Foot Pedals Positioned Under Operating Table



Photograph 8.10.11-2: Foot Pedals Operation by Surgeon

8.11.12 Mayo Table: Cables Bundle

The Mayo table is located adjacent to the operating table and includes a sterile cover. Multiple cables are bundled and clipped together on the Mayo table.



Photograph 8.10.12-1: Mayo Table with Sterile Cover and Cable Bundles

Chapter 9 References

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